Research Protocol

A study protocol on comparative randomised controlled trial of Homoeopathy -vs- allopathy in acute otitis media and its recurrence in Children

Central Council for Research in Homoeopathy

Abstract

Background: Acute otitis media (AOM) is one of the most common acute infections in children, and injudicious prescription of antibiotics may lead to increase of antibiotic-resistant cases. Homoeopathic treatment may provide a safer and more effective treatment. **Objective:** Earlier, a pilot study conducted by the Central Council for Research in Homoeopathy (CCRH) on eighty patients at a single centre showed non-inferiority results. This study shall be undertaken to substantiate the earlier findings. **Methods:** This will be an open-label, non-inferiority, randomised controlled (parallel arm) trial to be conducted on children in the age group of 2–12 years, suffering from AOM. The trial will include 240 children; each participant shall be randomly selected to receive either individualised homoeopathic medicine or symptomatic allopathic medicine. In case a child does not have ≥50% improvement with assigned treatment on day 3, he/she shall be given antibiotics. Children shall be treated/followed up for a period of 1 year to check recurrence, if any, in both the groups. The primary outcomes are changes in the Tympanic Membrane Examination Scale and Acute Otitis Media-Severity of Symptoms scale, time to improvement in pain through the Facial Pain Scale-Revised between the groups and recurrence (number of episodes, intensity and duration) of AOM between the groups at 1 year. **Discussion:** The study will consolidate the findings observed during a pilot study conducted by the CCRH at Jaipur, India. It is proposed to compare the role of individualised homoeopathy over allopathy in the treatment of AOM and to assess its role in controlling the recurrence.

Keywords: Acute otitis media, Allopathy, Children, Comparison, Homoeopathy

Introduction

Acute otitis media (AOM) is one of the most common disease in children. The usual symptomatic presentations characterising AOM are fever, irritability, otorrhoea, lethargy, vomiting, diarrhoea and hearing loss in some children.[1] The peak age-specific incidence is between six and fifteen months. Approximately 10% of children have an episode of AOM by three months of age and, approximately 50% to 85% of all children have experienced at least one AOM episode by three years of age.[2]

AOM is the general term embracing all inflammatory diseases of the middle ear, with particular involvement of the tympanic cavity.[3] The eustachian tube is the chief route by which infection reaches the middle ear. The most important cause is viral upper respiratory tract infection (URTI) followed by other opportunistic infections such as *Streptococcus pyogenes, Streptococcus pneumoniae, Haemophilus influenzae* and *Moraxella catarrhalis*.[4]

Access this article online

Quick Response Code:

Website: www.ijrh.org

DOI: 10.4103/ijrh.ijrh_57_19

Systematic reviews have demonstrated that the benefits of antibiotics must be weighed against the possible harms: for every 14 children treated with antibiotics one child experienced an adverse event (such as vomiting, diarrhoea or rash) that would not have occurred if antibiotics were withheld. Therefore clinical management should emphasise advice about adequate analgesia and the limited role for antibiotics.[2] i.e., preferring a watchful waiting in a majority of cases.[5,6]

Homoeopathy is the most popular treatment among the complementary and alternative medicine therapies sought for OM.[7] Studies have been conducted which show the

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Received: 25.07.2019; **Accepted:** 02.08.2019

How to cite this article: Central Council for Research in Homoeopathy. A study protocol on comparative randomised controlled trial of Homoeopathy -vs- allopathy in acute otitis media and its recurrence in children. Indian J Res Homoeopathy 2019;13:177-83.

positive role of homoeopathic medicines over placebo, in treating AOM.[8,9] Numerous clinical studies demonstrate that Homoeopathy accelerates early symptom relief in acute illnesses at much lower risk than conventional drug approaches. Evidence-based advantages for Homoeopathy include lower antibiotic fill rates during watchful waiting, fewer and less serious side effects, absence of drug–drug interactions and reduced parental sick leave from work.[10] In a prospective observational study carried out by one homoeopathic and four allopathy ear, nose and throat (ENT) practitioners, in treating acute paediatric OM, the homoeopathic single remedies were found to be beneficial in reducing the duration of suffering as well as the number of recurrences.[11] The existing research evidence on safety supports the pragmatic use of Homoeopathy in order to 'first do no harm' in the early symptom management of otherwise uncomplicated AOM.[10]

A pilot study conducted by Sinha *et al*.[12] compared individualised homoeopathic medicines in fifty millesimal (LM) potencies and symptomatic allopathic treatment including analgesics, antipyretics and anti-inflammatory drugs. Patients who did not improve were prescribed antibiotics at the 3rd day of treatment. Two different treatment therapies were compared which were found equally effective in AOM. However, symptomatic improvement was quicker in the Homoeopathy group, and there was a large difference in antibiotic requirements, favouring Homoeopathy.

In order to consolidate the findings observed in the pilot study, a multicentric study with larger sample size shall be undertaken to compare the treatment effects of Homoeopathy versus allopathy in AOM and further assess its role in controlling the recurrence.

Objectives

- Primary – To compare the efficacy of homoeopathic treatment with allopathic treatment in AOM through changes in AOM-Severity of Symptoms (AOM-SOS) scale and Tympanic Membrane Examination scale, "time to improvement" in pain and "recurrence" of AOM in both treatment groups
- Secondary – To evaluate the number of cases requiring antibiotic treatment, in both the groups, and to assess the quality of life (QOL) of children through Otitis Media-6 Health-related Quality of Life questionnaire.

Methods

Study design

This is a national, multicentric, open-label, non-inferiority, randomised controlled (parallel arm) trial that shall include 240 children, suffering from AOM. The trial will be conducted according to the principles of the Declaration of Helsinki.[13] The Institutional Ethical Committee of the Central Council for Research in Homoeopathy (CCRH) approved the trial protocol (reference number 1-172/2011-12/CCRH/CR/CTRI 2102 dated 17 September 2013). The clinical trials registry number is CTRI/2014/12/005294 dated 15/12/2014. The schedule of enrolment, intervention and assessments following the Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) guidelines is presented in Table 1.

Study setting

The study shall be conducted at the following ten centres under the CCRH: Central Research Institute (H), Noida (Uttar Pradesh); Central Research Institute (H), Kottayam (Kerala), now renamed as National Homoeopathy Research Institute for Mental Health; Regional Research Institutes (H), Jaipur (Rajasthan), Mumbai (Maharashtra), Guwahati (Assam), Imphal (Manipur), Gudivada (Andhra Pradesh), Drug Standardization Unit, Hyderabad (Andhra Pradesh) and Clinical Research Unit, Shillong (Meghalaya). ENT consultants shall be engaged to support the physical examination of ears and diagnosis and assess the patients for their symptom severity.

Eligibility criteria

Inclusion criteria are as follows:

a. Children aged 2–12 years who have earache of not more than 36 hours
b. Fullness/heaviness in ear with or without signs of URTI and pain in ear with or without fever
c. History of episode of AOM with proper record of diagnosis in the last 1 year
d. Tympanic membrane bulging with loss of landmarks and
e. Written informed consent and assessment as appropriate.

Exclusion criteria are as follows:

a. History of convulsions
b. Subperiosteal abscess of mastoid
c. Gross deviated nasal septum
d. Any discharge or history of discharge from ear
e. Suspected cases of gross adenoids (presenting with snoring and mouth breathing)
f. OM with effusion
g. Patients on antibiotics in the past 7 days
h. Patients on steroid treatment
i. Patients suffering from any systemic diseases.

Interventions

The children shall be allocated to either Homoeopathy or symptomatic Allopathy group in the ratio of 1:1.

Homoeopathic intervention – Group I

Homoeopathic medicines in centesimal potency (6C, 30C, 200C and 1M) shall be procured from Good Manufacturing Practices-compliant firms. These medicines shall be given following the Homoeopathy methodology of prescription. The selection of the individualised remedy (case analysis) will be carried out after the case history is taken by a homoeopath with more than 15 years of experience in classical Homoeopathy as described by Hahnemann.[14] The medicines shall be prescribed in centesimal potencies (6C/30C/200C/1M). Four pills of size 30 globules in the required potency will be administered. Indicated medicine will be repeated as per the

need of each case i.e., 2–6 hourly or even oftener, depending on the intensity of symptoms.

Allopathy treatment intervention – Group II

Allopathic medicines for the trial shall be procured from any of the standard company, approved by the CCRH in consultation with the ENT specialist. Only symptomatic treatment shall be given by the ENT specialist to the patients for the first 72 hours (3rd day of treatment), such as analgesics for pain, antipyretics for fever, anti-inflammatory for inflammation and decongestants for congestion.

Follow-up common to both groups

During the episode of acute otitis media

Each patient will be followed up on the 3rd, 7th, 10th and 21st days in person during each episode of AOM. AOM-SOS scale and Tympanic Membrane Examination Scale (TMES) will be used for the diagnosis and assessment of patients with AOM by the ENT specialist/investigator. The study timeline is summarised in Table 1.

On the 3rd day of follow-up, the ENT specialist will reassess the patients in both the groups on the AOM-SOS scale and TMES; if the symptomatic improvement is <50% based on the AOM-SOS scale comprising of seven discrete items, with score ranging from 0 to 14 [Table 1], and the TMES, then these patients shall be given antibiotics as per the ENT consultant irrespective of group allocation.

The Faces Pain Scale-Revised (FPS-R) will be used for the assessment of the intensity of pain during each AOM episode, on a daily basis. A diary containing FPS-R shall be provided to the parents of the enrolled children who will fill the scale twice daily. The parents will be advised to give paracetamol suspension to the child as per dose required in case of intolerable pain or emergency, whose details shall be noted in the dairy, and to contact the investigator as early as possible for further treatment.

After the episode of acute otitis media-21st day

On the 21st day of the episode of AOM, after thorough case taking in the case-recording format for chronic case, the totality of symptoms shall be derived and repertorisation of the symptoms shall be done by using a suitable repertory (manually or using computer-based homoeopathic software). After repertorisation and consultation with the *Materia medica*, single homoeopathic medicine shall be selected as the prescription with justification for the respective patient. The remedy is prescribed in centesimal potency (6C/30C/200C/1M), with each dose comprising four pills of 30 size globules, repeated as per the need of the case. The OM-6 scale shall be used for the assessment of QOL in children suffering from AOM. This will be filled with chronic case taking, at the 6th month and at the 12th month.

As AOM is a disease of periodical nature and has seasonal variation, after the acute phase subsides, the constitutional/miasmatic/intercurrent medicine should be prescribed after detailed case taking on the 21st day of follow-up of the first episode of AOM. Follow-up of the patients shall be done every month for a period of 1 year to observe the recurrence. If any episode of AOM arises during the period of follow-up, it shall be treated and followed as done during the first episode and forms shall be filled and enclosed with the case record. Each case shall be followed up for 1 year from the period of enrolment.

In allopathic group, the ENT specialist will treat the patient during the follow-up period of 1 year as per the present symptoms/complaints of the patient, if any. If the patient requires some treatment other than AOM episode, then the ENT specialist will treat him/her accordingly. The investigator and ENT specialist will keep the record of all treatments given to patients during the 1–year follow-up period.

Outcome

Primary outcome parameters

1. Changes in the TMES and AOM-SOS scale
2. Time to improvement in pain through the FPS-R between the groups
3. Recurrence (no. of episodes, intensity and duration) of AOM between the groups at 1 year.

Secondary outcome parameters

1. Usage of antibiotics in both the groups
2. Changes in the QOL of patients as evident from the OM-6 HRQOL scale at the 21st day, 6 months and 12 months.

Sample size

The sample size calculation based on a previous study of AOM showed 99% improvement in the conventional group and 95% in the Homoeopathy group by the 21st day. Assuming the non-inferiority margin of $\Delta = 0.04$, $\alpha = 0.05$ and power of 90% (beta error of 0.10) necessary to show the significance 100 patients are needed per group. Considering the dropout of about 20%, 120 cases shall be to be enrolled in each group to obtain a total of 240 patients.

Recruitment

The patients shall be included in the study from the general outpatient department of the institute/unit on the basis of the presenting symptom(s)/sign(s) of AOM as per the inclusion criteria.

Randomisation

Randomisation shall be done in block size of two by using RALLOC software (Philip Ryan, 1997. "RALLOC: Stata module to design randomized controlled trials," Statistical Software Components S319901, Boston College Department of Economics, revised 28 Jan 2018.). Centre-wise variable block randomisation will be done. Enrolment number of the patients shall be used for the purpose of randomisation. The ratio of allocation is 1:1. Initial randomisation shall be maintained for all follow-up visits.

Study duration

The study duration shall be of 2½ years including one year treatment period. This follow-up of 1 year is to observe the recurrence of acute episode, if any.

Table 1: Study time line

	Study period																		
Time point	**Enrolment**	**Allocation**	**Acute Episode in days**				**Post allocation in months**												**Close out**
	−1	**0 (B)**	**3rd**	**7th**	**10th**	**21st**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	
Enrolment																			
Eligibility screening	X																		
Informed consent and ascent (children aged 7-12 years and their parents)	X																		
Tympanic membrane examination by ENT specialist	X	X	X	X	X	X													
Allocation		X																	
Interventions																			
Homoeopathy		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Allopathy		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Assessments																			
Age	X																		
Height	X																		
Tympanic membrane examination	X	X	X	X	X	X													
AOM-SOS	X	X	X	X	X	X													
FPS-R + daily dairy	X	X	X	X	X	X													
OM-6 HRQOL						X						X						X	
Symptomatic assessment	X						X	X	X	X	X	X	X	X	X	X	X	X	
Recurrence of episodes							X	X	X	X	X	X	X	X	X	X	X	X	
Usage of antibiotics			X	X	X	X			X			X			X			X	
Telephonic follow-up		X	X	X	X	X													
Telephonic form							X	X	X	X	X	X	X	X	X	X	X	X	
AOM episodes' data table									X			X			X			X	X
Adverse event form			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Off study form																			X

AOM: Acute otitis media; SOS: Severity of Symptom scale; FPS-R: Facial Pain Scale-Revised; ENT: Ear, nose and throat; HRQOL: Health-Related Quality of Life

Statistical analysis

Data will be recorded on a pre-designed case-recording pro forma and will be managed on excel spreadsheet at each of the study centres. Finally, the data from all the centres will be combined together for analysis. Baseline characteristics of the study participants would be noted and compared in both the groups. The study outcome will be analysed according to parametric test for continuous data and non-parametric test for ordinal data after testing for normality. Baseline comparison would be considered for evaluating the randomisation effect. All the statistical results would be reported in 95% confidence interval with confidence level. For the outcomes of 'time to improvement' and 'recurrence', the approach of analysis would be based on 'time to an event data' (survival analysis). This would be done using Kaplan–Meier test. All analyses would be as per intention to treat. SPSS statistical software (IBM Statistical package for social sciences, version 20, India) would be used for data analysis.

Discussion

AOM is a problem requiring frequent visits of children with their parents to their family physician/general physician and antibiotics are commonly prescribed for this condition.[15] Further evaluation of studies to determine whether antibiotic therapy influences the outcome of AOM has been difficult to interpret because of the high rate of spontaneous recovery in children with the disease. Overuse and misuse of antibiotics are key factors contributing to antibiotic resistance. The general public, doctors and hospitals all play a role in ensuring proper use of the medications and minimising the development of antibiotic resistance. Studies conducted earlier have shown the positive role of homoeopathic medicines in the treatment of AOM.[5,8,9]

The protocol has been developed as per the SPIRIT guidelines[16] and shall generate data that can be reported as per the CONSORT guidelines[17] and Reporting data on homoeopathic treatments (RedHot) supplement for reporting randomised trials of Homoeopathy (RedHot).[18] It has been identified that the best way to assess a causal relationship between cure and medicine is the randomised controlled trial. Medicines prescribed as per homoeopathic principles covering the entire symptomatology and individual aspects of each patient shall be helpful in improving the overall health and well-being of the patient. Further, the response of the effects of the remedies prescribed shall verify the results of the pilot study.

Further, this study involves administration of individualised homoeopathic medicine with the involvement of experienced homoeopathic doctors in treating patients suffering from AOM, using validated assessments, which will be amenable to the profession at large, thus covering all the domains of the model validity of homoeopathic trials.[19]

Contributors

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Financial support and sponsorship

This study shall be financially supported by the Central Council for Research in Homoeopathy.

Conflicts of interest

None declared.

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होम्योपैथी का एक तुलनात्मक यादृच्छिक नियंत्रित परीक्षण एलोपैथी बनाम होम्योपैथी

पृष्ठभूमि : एक्यूट ओटाइटिस मीडिया (एओएम) बच्चों में सबसे सामान्य संक्रमणों में से एक है और एंटीबायोटिक दवाओं के हानिकारक नुस्खे से एंटीबायोटिक प्रतिरोधी मामलों में वृद्धि हो सकती है। होम्योपैथी उपचार अधिक प्रभावी उपचार प्रदान कर सकता है। उद्देश्यः पहले एक केंद्र पर 80 मरीजों पर सीसीआरएच द्वारा किए गए प्रारंभिक अध्ययन ने समान परिणाम दिखाए। यह अध्ययन पहले के निष्कर्षों को प्रमाणित करने के लिए किया जाएगा।

विधि : यह एक खुला लेवल, गैर हीनता, यादृच्छिक नियंत्रित (समानांतर भुजा) का परीक्षण होगा जो एक्यूट ओटाईटिस मीडिया से पीड़ित 2–12 वर्ष की आयु के बच्चों पर किया जाएगा। परीक्षण में 240 बच्चे शामिल होंगे, प्रत्येक प्रतिभागी को व्यक्तिगत रुप से होम्योपैथी दवा या रोगसूचक एलोपैथिक दवा प्राप्त करने के लिए यादृच्छिक रुप से चुना जाएगा। यदि किसी बच्चे को तीन दिन में निर्धारित उपचार के साथ ≥ 50ः सुधार नहीं होता है, तो उन्हें एंटिबायोटिक दवा दी जाएगी। दोनों समूहों में बच्चों की किसी भी समय पुनरावृत्ति की जांच के लिए एक वर्ष की अवधि तक बच्चों का इलाज/अनुसरण किया जाएगा। समूहों और पुनरावृत्ति के बीच एफपीएस–आर (फेशियल दर्द मापक–संशोधित) के माध्यम से दर्द में सुधार के लिए प्राथमिक परिणाम टिपेनीक मेम्ब्रेन परीक्षण मापक (टीएमईएस) और एक्यूट ओटाईस मीडिया–गंभीरता (एओएम–एसओएस) मापक में परिवर्तन है और एक वर्ष में समूहों के बीच (प्रकरणों की संख्या, मात्रा, अवधि) की पुनरावृत्ति रखा गया है।

चर्चा : अध्ययन जयपुर, भारत में सीसीआरएच द्वारा आयोजित एक प्रारंभिक अध्ययन के दौरान देखे गए निष्कर्षों को समेकित करेगा। एओएम के उपचार में एलोपैथी पर व्यक्तिगत होम्योपैथी की भूमिका की तुलना करना और पुनरावृत्ति को नियंत्रित करने में इसकी भूमिका कर आकलन करना प्रस्तावित है।

Un essai comparatif randomisé et contrôlé de l'homéopathie contre l'allopathie dans les cas d'otite moyenne aiguë et de sa récurrence chez les enfants

Objectif: L'otite moyenne aiguë (OMA) est l'une des infections aiguës les plus courantes chez les enfants et la prescription non judicieuse d'antibiotiques peut entraîner une augmentation du nombre de cas de résistance aux antibiotiques. L'homéopathie peut fournir un traitement plus sûr et plus efficace. Une étude pilote réalisée précédemment par le CCRH sur 80 patients d'un centre avait montré des résultats de non infériorité. Cette étude est entreprise pour corroborer les résultats antérieurs.

Méthode: Il s'agira d'un essai ouvert, de non infériorité, contrôlé et randomisé (traitement parallèle) mené auprès d'enfants âgés de 2 à 12 ans et souffrant d'otite moyenne aiguë. L'essai comportera 240 enfants et chaque participant sera sélectionné au hasard pour recevoir soit un médicament homéopathique personnalisé, soit un médicament allopathique symptomatique. Si un enfant ne présente pas une amélioration d'au moins 50% avec le traitement attribué le troisième jour, il recevra des antibiotiques. Les enfants doivent être traités / suivis pendant un an pour vérifier la récurrence, le cas échéant, dans les deux groupes. Le critère de jugement principal est la modification de l'échelle d'examen de la membrane tympanique (TMES) et de l'échelle de gravité des symptômes de l'otite aiguë (OMA-SOS), le temps nécessaire à l'amélioration de la douleur grâce au FPS-R (échelle de douleur faciale révisée) dans les groupes et la récurrence (nombre d'épisodes, intensité, durée) de l'OMA entre les groupes à 1 an.

Discussion: L'étude consolidera les résultats observés lors d'une étude pilote menée par le CCRH à Jaipur en Inde. Il est proposé de comparer le rôle de l'homéopathie personnalisée par rapport à l'allopathie dans le traitement de l'OMA et d'évaluer son rôle dans le contrôle de la récurrence.

Un ensayo comparativo aleatorizado y controlado de homeopatía –vs- alopatía en otitis media aguda y su recurrencia en niños

Objetivos: La otitis media aguda (OMA) es una de las infecciones agudas más comunes en niños. La prescripción no juiciosa de antibióticos puede provocar un aumento de los casos resistentes a antibióticos. La homeopatía puede proporcionar un tratamiento más seguro y más eficaz. El estudio piloto anterior, realizado por el CCRH en 80 pacientes en un centro, mostró resultados de no inferioridad. Este estudio se realiza para corroborar los hallazgos anteriores.

Método: Será un ensayo controlado (con brazo paralelo), aleatorizado, de diseño abierto y de no inferioridad, que se realizará en niños del grupo de edades entre 2 y 12 años, con una otitis media aguda. El ensayo incluirá 240 niños, de los que cada participante será seleccionado de forma aleatoria para recibir un medicamento homeopático individualizado o bien un medicamento alopático sintomático. En caso de que un niño no muestre una mejoría ≥50% con el tratamiento asignado en el día tres, recibirá un antibiótico. Los serán tratados/seguidos durante un periodo de hasta un año para checar las recidivas (si las hay) en ambos grupos. El parámetro principal es el cambio en la escala de examen de la membrana timpánica (TMES, *Tympanic Membrane Examination Scale*) y la escala de gravedad de los síntomas de la otitis media aguda (AOM SOS, *Acute Otitis Media-Severity of Symptoms Scale*), el tiempo hasta la mejoría del dolor con la escala de dos facial revisada (FPS-R, *Facial Pain Scale-Revised*) entre los grupos y las recidivas (número de episodios, su intensidad y su duración) de la OMA entre los grupos al año.

Discusión: El estudio consolidará los hallazgos observados durante un estudio piloto realizado por el CCRH en Jaipur, India. Se propone que compare el papel de la homeopatía individualizada frente a la alopatía en el tratamiento de la OMA y que evalúa su papel en controlar las recidivas.

Eine vergleichende randomisierte kontrollierte Studie zur Homöopathie - vs. Allopathie bei akuter Otitis media und deren Rezidiv bei Kindern

Ziel: Akute Mittelohrentzündung (AOM) ist eine der häufigsten akuten Infektionen bei Kindern. Eine unsachgemäße Verschreibung von Antibiotika kann zu einer Zunahme von Fällen mit Antibiotikaresistenz führen. Eine homöopathische Behandlung kann eine sicherere und wirksamere Behandlung bieten. Eine frühere Pilotstudie, die von CCRH an 80 Patienten im onecentre durchgeführt wurde, zeigte, dass die Ergebnisse nicht minderwertig waren. Diese Studie wird durchgeführt, um die früheren Ergebnisse zu untermauern

Methode: Dies ist eine offene, nicht minderwertige, randomisierte, kontrollierte (Parallelarm-) Studie, die an Kindern im Alter von 02 bis 12 Jahren mit akuter Mittelohrentzündung durchgeführt wird. Die Studie wird 240 Kinder umfassen. Jeder Teilnehmer wird nach dem Zufallsprinzip ausgewählt, um entweder ein individualisiertes homöopathisches Arzneimittel oder ein symptomatisches allopathisches Arzneimittel zu erhalten. Wenn sich ein Kind am dritten Tag mit der zugewiesenen Behandlung nicht um ≥50% bessert, erhält es Antibiotika. Kinder müssen für einen Zeitraum von einem Jahr behandelt / überwacht werden, um ein Wiederauftreten in beiden Gruppen zu überprüfen. Das primäre Ergebnis sind Veränderungen in der Tympanic Membrane Examination Scale (TMES) und der Acute Otitis Media-Severity of Symptoms-Skala (AOM-SOS), die Zeit bis zur Schmerzverbesserung durch FPS-R (Facial Pain Scale-Revised) zwischen den Gruppen und ein erneutes Auftreten (Anzahl der Episoden, Intensität, Dauer) der AOM zwischen den Gruppen nach 1 Jahr.

Diskussion: Die Studie wird die Ergebnisse einer von CCRH in Jaipur, Indien, durchgeführten Pilotstudie konsolidieren. Es wird vorgeschlagen, die Rolle der individualisierten Homöopathie gegenüber der Allopathie bei der Behandlung von AOM zu vergleichen und ihre Rolle bei der Kontrolle des Wiederauftretens zu bewerten.

順勢療法-vs-對抗療法的隨機對照試驗，兒童急性中耳炎及其復發性之比較

目的：急性中耳炎（AOM）是兒童最常見的急性感染之一，不良的抗生素處方可能導致耐藥性的病例增加。順勢療法可能提供一種更安全、更有效的治療方法。早期由CCRH對一個中心的80名患者進行的試點研究顯示出非劣效性結果。本研究旨在證實先前的發現。

方法：採用開放性、非劣效性、隨機對照（平行分支）試驗，對2～12歲兒童急性中耳炎進行研究。試驗將包括240名兒童，每名參與者應隨機選擇接受個人化順勢療法藥物或症狀性的對抗療法藥物。如果在第三天接受指定治療後，如果兒童沒有≥50%的改善，他們將接受抗生素治療。兩組兒童應接受為期一年的治療／跟進，以檢查復發情況（如有）。主要結果是鼓膜檢查量表（TMES）和急性中耳炎症狀嚴重程度（AOM-SOS）量表的變化，各組間通過FPS-R（面部疼痛量表修訂）改善疼痛的時間和兩組間AOM復發（發作次數、強度、持續時間）的時間以及組別間第1年AOM的復發

討論：該研究將鞏固印度齋浦爾CCRH進行的試點研究中觀察到的結果。本研究旨在比較個人化順勢療法與對抗療法在AOM治療中的作用，並評估其在控制復發中的作用。