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The efficacy of nasal cavity lavage with a physiological saline solution in prevention of recurrent acute otitis media: a pilot randomised controlled study

Submission date
20/01/2008

Recruitment status
No longer recruiting

Registration date
16/04/2008

Overall study status
Completed

Last Edited
16/04/2008

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

We believe that regular nasal irrigation with a physiological saline solution decreases the occurrence of acute otitis media (AOM) and recurrent acute otitis media (rOMA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Comité d'éthique de la recherche du CHU Saint-Justine on the 28th May 2007 (ref: 2510), last amended 8th January 2008.

Primary study design
Interventional

Study design
Randomised controlled pilot project

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Recurrent acute otitis media

Interventions
Intervention group:
Nasal irrigation with a physiological saline solution. A 0.9% saline solution is used.
1. If the child is not capable of blowing his nose: 1 cc (full dropper) per nostril, repeated twice, performed four times a day (QID) or six times daily during a respiratory infection
2. If the child is capable of blowing his nose: 5 vaporisations per nostril, blow nose and repeat a second time, perform QID or six times daily during a respiratory infection

Control group:
Patients in the control arm do not perform nasal irrigations.

Treatment lasts 3 months and there are two follow-up visits at 6 weeks intervals.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Saline solution

Primary outcome(s)
Incidence of recurrent acute otitis media (rAOM) defined as the occurrence of two distinct episodes of acute otitis media during the 3-month study period.

Key secondary outcome(s)
1. Occurrence of 1 episode of acute otitis media during the 3-month study period
2. Occurrence of adverse events

Completion date
01/06/2008

Eligibility

Key inclusion criteria
1. Age is between 6 months and 5 years old (exclusively), either sex
2. Recurrent acute otitis media (AOM) (diagnosed by paediatrician or referring general practitioner):
2.1. Four AOM within 6 months
2.2. Six AOM or more within 1 year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
5 Years

Sex
All

Key exclusion criteria
1. Parents refuse to participate
2. Known disease or syndrome modifying the normal anatomy or physiology or the upper respiratory tract (Downs, Apert, Crouzon, mucopolysaccharidosis, cranio-cerebral trauma, etc.)
3. Malformations:
3.1. Craniofacial, skull base or nose
3.2. Complete or submucous cleft palate
4. Immunodeficiency:
4.1. Congenital (according to paediatrician or immunologist)
4.2. Acquired (human immunodeficiency virus [HIV], chemotherapy)
5. Ciliary dysfunction (according to paediatrician or pneumologist)
6. Tympanic membrane perforation
7. Cholesteatoma
8. Acute complication of AOM (intra- or extra-cranial)
9. History of ear, nose and throat (ENT) surgery (adenoidectomy, tonsillectomy, myringotomy or other)
10. Intra-nasal or systemic corticosteroid use (pulmonary steroids not excluded)

11. Adenoid or tonsil hypertrophy with suspicion of obstructive apnoea
12. Multiple allergies to antibiotics
13. Insufficient comprehension of written or spoken French by parents

Date of first enrolment
24/09/2007

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
Canada

Study participating centre
3175 Cote Sainte-Catherine
Montreal
Canada
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Sponsor information

Organisation
Sainte-Justine Hospital Research Centre (Centre de recherche du CHU Sainte-Justine) (Canada)

ROR
https://ror.org/01gv74p78

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sainte-Justine Hospital Research Centre (Centre de recherche du CHU Sainte-Justine) (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration