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Are topical antibiotics required for the treatment of otitis externa?

Submission date 23/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/10/2006	**Overall study status** Completed	
Last Edited 29/01/2010	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Desmond Nunez

Contact details
Academic Dept. of Otolaryngology
North Bristol NHS Trust
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NRR Pub ID N0234117609

Study information

Scientific Title

Study objectives
That there is no difference between plain steroid drops or combination steroid and antibiotic drops in the resolution of otitis externa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Otitis Externa

Interventions
Aural toilet and Vista Metasone topical drops versus Aural toilet and topical Vista Metasone-N over a 2 week period

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Plain steroid drops or combination steroid and antibiotic drops

Primary outcome measure
Subjects' visual analogue symptom scores for otitis externa pre and post treatment.

Secondary outcome measures

Observer' s visual analogue scores for signs of otitis externa pre and post treatment.

Overall study start date
01/06/2003

Completion date
01/12/2005

Eligibility

Key inclusion criteria
Patients with otitis externa presenting to the otolaryngology emergency clinic of an acute urban teaching hospital.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
55

Key exclusion criteria
1. Patients under the age of 18 years
2. Diabetics
3. Immunocompromise
4. Evidence of concurrent middle ear disease
5. Non-English speakers
6. Mental impairment
7. Allergy to the medicine
8. Previous treatment with the trial medication
9. Patients declining to participate

Date of first enrolment
01/06/2003

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Dept. of Otolaryngology
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

Sponsor details
Research & Development Support Unit
Southmead Hospital
Bristol
England
United Kingdom
BS10 5NB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
Internal: Department of Otolaryngology, North Bristol NHS Trust (own account) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2009		Yes	No