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Gentamicin hydrocortisone formulations in Otitis Externa Study (GOES)

Submission date 27/01/2005	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/05/2005	**Overall study status** Stopped	
Last Edited 13/08/2012	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ian Williamson

Contact details
Primary Medical Care
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton
United Kingdom
SO16 5ST
+44 (0)2380 241071
igw@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Gentispray 001

Study information

Scientific Title
A double blind, placebo controlled, multi-centre general practice study comparing the efficacy and tolerability of a spray with a drop presentation of Gentamicin and Hydrocortisone in patients with Otitis Externa.

Acronym
GOES

Study objectives
To compare the efficacy and tolerability of a spray versus a drop presentation of gentamicin and hydrocortisone for the treatment of otitis externa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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

Interventions
Double blind, randomised, parallel group study comparing two groups of 60 patients on active treatment (spray or drop) and two groups of 15 placebo (spray or drop)

Please note that as of 13/08/2012 the record was updated to show that the trial was stopped in November 2007 due to lack of funding and patient recruitment issues.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gentamicin, hydrocortisone

Primary outcome measure
Total Efficacy Score (TSS) at day 10

Secondary outcome measures
TSS and the Global Impression Score at day 24, individual components of the TSS, and Patient Diary scores.

Overall study start date
01/09/2004

Completion date
31/08/2005

Reason abandoned (if study stopped)
Lack of funding, Patient recruitment issues

Eligibility

Key inclusion criteria
150 adult (over 18 yrs) patients presenting with bacterial otitis externa in general practice.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. A known or suspected perforation of the eardrum
2. Otitis externa secondary to otitis media
3. Chronic or fungal otitis externa, or a primary dermatological condition affecting the ear
4. Furuncles or infected mastoid cavities
5. A body temperature exceeding 38.3°C (101.0°F)
6. Abnormalities of the external auditory meatus, such as exostosis, tumours, etc.
7. Received any systemic antibiotic treatment for any indication in the last two weeks

8. Administered any topical ear preparation to the affected ear(s) in the last two weeks (including over the counter [OTC] preparations)
9. Hypersensitive to aminoglycoside antibiotics or corticosteroids or preservatives
10. Suffering from dizziness or vertigo
11. Is the patient diabetic or immunosuppressed
12. Taking systemic antibiotics
13. Administering any other topical ear preparation
14. Incapable of administering topical ear prepartions
15. In the investigators judgement, likely to be unreliable or uncooperative with the requirements and evaluation procedures outlined in this protocol
16. In the investigators judgement, showing clinical evidence of any unstable or clinically significant medical illness that may obscure the results of treatment

Date of first enrolment
01/09/2004

Date of final enrolment
31/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Medical Care
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
Acorus Therapeutics Ltd (UK)

Sponsor details
High Crane Lodge
Hamsterley
Co. Durham
United Kingdom
DL13 3QS

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Acorus Therapeutics Ltd (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