# Gentamicin hydrocortisone formulations in Otitis Externa Study (GOES)

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

## Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

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# 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