

# Gentamicin hydrocortisone formulations in Otitis Externa Study (GOES)

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

**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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

Total Efficacy Score (TSS) at day 10

**Key secondary outcome(s))**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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 preparations
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**

United Kingdom

England

**Study participating centre**

**Primary Medical Care**

Southampton

United Kingdom

SO16 5ST

## **Sponsor information**

**Organisation**

Acorus Therapeutics Ltd (UK)

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Acorus Therapeutics Ltd (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration