

# Efficacy of hydroxyethyl starch (HES) 130/0.4 versus glucose solution in haemodilution therapy of idiopathic sudden hearing loss: a dose-finding, double-blind multicentre trial

<b>Submission date</b> 03/02/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/02/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/02/2008	<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

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

HS-13-26-EU

# Study information

## Scientific Title

## Study objectives

Objective: Obtain first data on HES 130/0.4 (hydroxyethyl starch) as monotherapy in patients with acute idiopathic sudden sensorineural hearing loss (ISSNHL).

## 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

Sudden hearing loss

## Interventions

Infusion of 750 ml per day with HES 45 g per day (group H), 30 g per day (M), 15 g per day (L), or glucose 5% (G) acting as 'placebo' control over 6 days.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Hydroxyethyl starch

### **Primary outcome measure**

Absolute hearing gain (AHG) in decibel at Day 7, calculated as mean audiometric hearing threshold (MAHT) at baseline minus MAHT at Day 7, whereby MAHT was the arithmetic mean of the hearing thresholds in dB at the main speech frequencies of 0.5, 1, 2, 3, and 4 kilohertz

### **Secondary outcome measures**

Efficacy:

1. AHG at other timepoints (i.e. Days 3, 14, and 90)
2. AHG based on geometric MAHT
3. Hearing gain based on the Schwab/Ewert formula i.e. the arithmetic mean of the delogarithmed pure tone thresholds
4. AHG based on arithmetic and geometric MAHT calculated only on speech frequencies with an initial hearing loss of 20 dB or more
5. Outcome categorised in complete/partial/no recovery or deterioration
6. Changes of subjective hearing, vertigo, and tinnitus

Safety:

1. Adverse events
2. Laboratory parameters (haematology, haemostasis, clinical chemistry, urinalysis)
3. Vital signs

### **Overall study start date**

01/11/2000

### **Completion date**

31/12/2002

## **Eligibility**

### **Key inclusion criteria**

210 inpatients with first-time idiopathic sudden sensorineural hearing loss (ISSNHL) of 20 dB or more at two or more frequencies and 95 dB or less at all of the speech frequencies (0.5, 1.0, 2.0, 3.0, 4.0 kHz) with respect to the other (normal) ear for up to 7 days.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

210

### **Key exclusion criteria**

Not provided at time of registration

### **Date of first enrolment**

01/11/2000

**Date of final enrolment**

31/12/2002

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

HNO-Klinik Krankenhaus Dresden-Friedrichstadt

Dresden

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01067

## **Sponsor information**

**Organisation**

Fresenius Kabi Deutschland GmbH (Germany)

**Sponsor details**

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**Sponsor type**

Industry

**ROR**

<https://ror.org/01v376g59>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Fresenius Kabi Deutschland GmbH (Germany) (ref: HS-13-26-EU)

# 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