

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

Submission date 03/02/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 09/02/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/02/2008	Condition category Ear, Nose and Throat	☐ Individual participant data
		☐ 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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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Germany
01067

Sponsor information

Organisation

Fresenius Kabi Deutschland GmbH (Germany)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration