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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

Registration date
09/02/2005

Overall study status
Completed

Last Edited
18/02/2008

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
Fresenius Kabi Deutschland GmbH (Germany)

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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