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Tabriz University of Medical Sciences trial of inpatient intravenous urographin plus corticosteroid versus outpatient oral corticosteroid therapy in the Sudden Sensorineural Hearing Loss

Submission date 11/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/10/2006	**Overall study status** Completed	
Last Edited 02/09/2021	**Condition category** Ear, Nose and Throat	

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
N/A

Study information

Scientific Title
Tabriz University of Medical Sciences trial of inpatient intravenous urographin plus corticosteroid versus outpatient oral corticosteroid therapy in the Sudden Sensorineural Hearing Loss

Acronym
SSHL trial

Study objectives
Sudden Sensorineural Hearing Loss is a diagnosis typically made if there is a greater than 20 dB hearing loss over at least three frequencies on audiometric testing.

Hypothesis:
In-hospital and vigorous treatment with intravenous corticosteroid and urographin will improve the outcome of patients with a sudden sensorineural hearing loss when compared to an outpatient oral corticosteroid therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Institutional Board Review and Ethics Committee, a section of Research Deputy of Faculty of Medicine at Tabriz University of Medical Sciences (TUMS).

Study design
Interventional, controlled clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sudden Sensorineural Hearing Loss

Interventions

The trial is not a randomised one, as we had two groups: those hospitalised and those managed on outpatient. Hospitalisation was made on the basis of patient's request.

Inpatient group received intravenous corticosteroid and intravenous urographin, while outpatient group received oral corticosteroid.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Corticosteroid and urographin

Primary outcome measure
Hearing recovery as shown by pure tone average on audiogram.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2003

Completion date
01/01/2005

Eligibility

Key inclusion criteria
1. Aged over 12 years
2. A greater than 20 dB hearing loss over at least three frequencies on audiometric testing

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
60

Total final enrolment
51

Key exclusion criteria

1. General medical condition necessitating a specific therapy
2. Incompliance to the medications

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2005

Locations

Countries of recruitment
Iran

Study participating centre
Daneshgah Street
Tabriz
Iran
0098411

Sponsor information

Organisation
Tabriz University of Medical Sciences (TUMS) (Iran)

Sponsor details
Danshgah Street
Tabriz
Iran
0098411

Sponsor type
University/education

ROR
https://ror.org/04krpx645

Funder(s)

Funder type
University/education

Funder Name
Tabriz University of Medical Sciences (TUMS) (Iran)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2008	02/09/2021	Yes	No