

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/10/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/09/2021	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Hearing recovery as shown by pure tone average on audiogram.

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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)

ROR

<https://ror.org/04krpx645>

Funder(s)

Funder type

University/education

Funder Name

Tabriz University of Medical Sciences (TUMS) (Iran)

Results and Publications

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