

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

<b>Submission date</b> 11/08/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/10/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/09/2021	<b>Condition category</b> 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

**Contact name**  
Dr Javad Totonchi

**Contact details**  
Daneshgah Street  
Imam Hospital  
ENT ward  
Tabriz  
Iran  
0098411

## 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**

Daneshgah 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?
<a href="#">Results article</a>		01/07/2008	02/09/2021	Yes	No