

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of a middle ear surgical simulator as an educational tool for ENT residents in stapes surgery

Protocol summary

Summary

This is part of a multicenter study. Colleagues from George Washington University will provide the simulators. This study has 4 phases. First, anatomic structure of the simulator will be investigated by professional otologists. Participants will get familiar with device and an educational video will be played for them; then residents will be divided to 3 groups: 1) doing surgery on simulator, 2) removing a holed ball from the simulator, 3) not using simulator. After this phase all of the participants will perform surgery on simulator. All of the surgeries will be recorded and scored by 3 experts. After this phase all of the participants will perform surgery in the operating room and will be evaluated. Evaluation will be repeated after 3, 6, and 12 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050110041N2**

Registration date: **2013-06-12, 1392/03/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Ali Kouhi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 3037

Email address

a-kouhi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences & George Washington University

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of a middle ear surgical simulator as an educational tool for ENT residents in stapes surgery

Public title

Evaluation of a middle ear surgical simulator as an educational tool for ENT residents in stapes surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criterion: residents of otolaryngology in Tehran University of Medical Sciences. Exclusion: refusal to attend the project; previous experience with simulator.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Ghods st.

City

Tehran

Postal code**Approval date**

2013-02-25, 1391/12/07

Ethics committee reference number

91-04-48-20441-79592

Health conditions studied**1****Description of health condition studied**

otosclerosis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Performance in stapedectomy

Timepoint

1, 3, 6 and 12 months

Method of measurement

Observation

Secondary outcomes**1****Description**

Performance on simulator

Timepoint

12th month

Method of measurement

Observation

Intervention groups**1****Description**

practice on removing ball from a hole. This group is designed to study if practicing on simulator is a confounding factor and whether it only improves psychomotor or improves stapedectomy surgical skill.

Category

Treatment - Surgery

2**Description**

practice on simulator

Category

Treatment - Surgery

3**Description**

no simulator. this is a control group and is used to compare results with other groups.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir-Alam hospital

Full name of responsible person

Ali Kouhi

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Miss. Nouruz zadeh

Street address

Ghods, st. research office

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Kouhi
Position
Assistant professor
Other areas of specialty/work
Street address
Amir-Alam Hospital
City
Tehran
Postal code
Phone
+98 21 6670 3037
Fax
Email
a-kouhi@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Kouhi
Position
Assistant professor
Other areas of specialty/work

Street address
Amir- Alam Hospital
City
Tehran
Postal code
Phone
+98 21 6670 3037
Fax
Email
a-kouhi@tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Kouhi
Position
Assistant professor
Other areas of specialty/work
Street address
Amir-Alam Hospital
City
Tehran
Postal code
Phone
+98 21 6670 3037
Fax
Email
a-kouhi@tums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty