

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessing temperature \_ controlled radiofrequency tonsil ablation and CO<sub>2</sub>- laser cryptolysis on treatment of chronic tonsillitis with caseum.

#### Protocol summary

##### Summary

Study design: randomized clinical trial. Inclusion criteria: patients upper than 18 years old referred to Besat Hospital clinic with chronic tonsillitis with caseum who had symptoms such as halitosis(with positive Finklestien smell test ) or feeling of foreign body and chronic irritation of tonsils; patients who had no periodontal disease, gingivitis or other systemic disease that result in halitosis such as hepatorenal and pulmonary and gastroenterological disease or diabetes mellitus , sinusitis, nasopharyngeal , oropharyngeal or laryngeal cancer in history and physical examination; patients who had no contraindications for radiofrequency of tonsils such as having cardiac pace maker, immunodeficiency disease or coagulation disorders and patients who had no limitation for CO<sub>2</sub>- laser. cryptolysis such as anatomical orophryngeal anomalies or mallampati grading 3 or 4. Sample size: 50. Study objective: finding a safe and more cost-effective way to treat chronic tonsillitis with caseum

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201303233186N3**  
Registration date: **2013-08-23, 1392/06/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-23, 1392/06/01

##### Registrant information

##### Name

Farnaz Hashemian

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3827 9001

##### Email address

hashemian@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hamedan University of Medical Sciences

##### Expected recruitment start date

2013-05-22, 1392/03/01

##### Expected recruitment end date

2014-11-22, 1393/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing temperature \_ controlled radiofrequency tonsil ablation and CO<sub>2</sub>- laser cryptolysis on treatment of chronic tonsillitis with caseum.

##### Public title

Assessing temperature \_ controlled radiofrequency tonsil ablation and CO<sub>2</sub>- laser cryptolysis on treatment of chronic tonsillitis with caseum.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients upper than 18 years old referred to Besat Hospital clinic with chronic tonsillitis with caseum who had symptoms such as halitosis(with positive Finklestien smell test ) or feeling of foreign body and chronic irritation of tonsils; patients who had no periodontal disease, gingivitis or other systemic disease

that result in halitosis such as hepatorenal and pulmonary and gastroenterological disease or diabetes mellitus , sinusitis, nasopharyngeal , oropharyngeal or laryngeal cancer in history and physical examination; patients who had no contraindications for radiofrequency of tonsils such as having cardiac pace maker, immunodeficiency disease or coagulation disorders and patients who had no limitation for CO<sub>2</sub>- laser. Exclusion criterion: cryptolysis such as anatomical oropharyngeal anomalies or mallampati grading 3 or 4.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 50

**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**

Hamedan university of medical

**Street address**

Hamedan university of medical sciences, Shahid Fahmideh street, Hamedan.

**City**

Hamedan

**Postal code**

65178

**Approval date**

2013-04-08, 1392/01/19

**Ethics committee reference number**

16/35/9/63/د/پ

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

Chronic tonsillitis with caseum

**ICD-10 code**

J35

**ICD-10 code description**

Chronic tonsillitis

**Primary outcomes****1****Description**

Halitosis

**Timepoint**

Before, 1 week, 1 month, 6 months after intervention

**Method of measurement**

Visual analog scale questionnaire

**2****Description**

Feeling of foreign body

**Timepoint**

Before, 1 week, 1 month, 6 months after intervention

**Method of measurement**

Visual analog scale questionnaire

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

Post intervention pain

**Timepoint**

1, 3 and 7 days after intervention

**Method of measurement**

Visual analog scale

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

Intervention : temperature \_ controlled radiofrequency tonsil ablation

**Category**

Treatment - Other

**2****Description**

Control : CO<sub>2</sub>- laser cryptolysis of tonsils

**Category**

Treatment - Other

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

Besat hospital, ENT clinic

**Full name of responsible person**

**Street address****City**

Hamedan

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Tavilani Heydar

**Street address**

Hamedan University of Medical Sciences, Shahid Fahmideh street, Hamedan

**City**

Hamedan

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Farnaz Hashemian

**Position**

Associate professor

**Other areas of specialty/work****Street address**

Besat hospital, shahid Beheshti Blvd., Hamedan

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+98 81 1264 0047

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Farnaz Hashemian

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Associate professor

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**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*