# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Comparing the effect of honey mouthwash with hydrogen peroxide mouthwash on oral lesions healing in patients with Pemphigus

## Protocol summary

**Summary**

This study assessed the efficacy of mouthwash with honey compared with hydrogen peroxide in oral lesions healing in Pemphigus patients. A randomized clinical trial was carried on 49 patients with oral pemphigus lesions. Patients randomly divided into experimental and control groups. Experimental group received honey mouthwash 12.5%, daily, half an hour after each meal. Control group received H2O2 mouthwash 1.5%, daily, half an hour after each meal. Patients were assessed for 10 days. Data were collected by questionnaire: Oral Mucositis Visual Assessment Guide of WHO, visual analog scale of pain intensity and time Diaries.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138902142846N4**
Registration date: **2010-06-16, 1389/03/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2010-06-16, 1389/03/26

**Registrant information**

**Name**

Tahereh Ashktorab

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2222 1543

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

private

**Expected recruitment start date**

2009-10-07, 1388/07/15

**Expected recruitment end date**

2010-02-04, 1388/11/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effect of honey mouthwash with hydrogen peroxide mouthwash on oral lesions healing in patients with Pemphigus

**Public title**

Efficacy of honey mouthwash on oral lesions healing in patients with Pemphigus

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: patients with oral pemphigus lesions (grades of 1-3 were considered as oral ulcers), treated with classical pemphigus (a corticosteroid and immunosuppressive). Exclusion criteria: any broad spectrum antibiotics in the patient medication instructions, underlying disease (diabetes, infections, mouth and teeth), history of allergy to honey, history of chemotherapy and radiation therapy for head and neck and lesions worsening during using honey mouthwash (in this case, treatment will be returned to the routine).

**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**
The International and Virtual Branch of Shahid Beheshti University of Medical Sciences
**Street address**
NO19, Shahid Abaspoor St, Next to Shahid Hemmat Bridge, Valiasre Ave
**City**
Tehran
**Postal code**
3693-14155
**Approval date**
2009-10-20, 1388/07/28
**Ethics committee reference number**
675/116

## Health conditions studied

### 1

**Description of health condition studied**
oral lesions in pemphigus
**ICD-10 code**
L10
**ICD-10 code description**
Pemphigus

## Primary outcomes

### 1

**Description**
grade of oral lesions
**Timepoint**
at the begining and then every other day for ten days
**Method of measurement**
Oral Mucositis Visual Assessment Guide of WHO

## Secondary outcomes

### 1

**Description**
healing erythema
**Timepoint**
every other day/and till 10 day
**Method of measurement**
Oral Mucositis Visual Assessment Guide of WHO

### 2

**Description**
Reducing pain in oral lesions
**Timepoint**
every other day/and till 10 day
**Method of measurement**
visual analog scale of pain intensity

### 3

**Description**
Improvement patient’s dietary intake
**Timepoint**
every other day/and till 10 day
**Method of measurement**
Oral Mucositis Visual Assessment Guide of WHO

## Intervention groups

### 1

**Description**
Intervention group: honey mouthwash 12.5%, daily, half an hour after each meal
**Category**
Treatment - Other

### 2

**Description**
Control group: H2O2 mouthwash 1.5%, daily, half an hour after each meal
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shohada Hospital
**Full name of responsible person**
**Street address**
**City**
Tehran

**2**

**Recruitment center**
**Name of recruitment center**
Loghman Hospital
**Full name of responsible person**
**Street address**
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Private
**Full name of responsible person**
Mahshid Parvin
**Street address**
NO7-Baradaran AbasyAL- Amini Av-Karimi Av-Dezashib Av-Shemiran
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Private
**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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Dr. Tahere Ashktorab
**Position**
PhD of Nursing
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*