

# Comparing benzydamine with placebo in the prevention of radiation-induced mucositis in head and neck cancer patients in Imam Hossein Hospital, Iran

<b>Submission date</b> 20/11/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/02/2010	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Ahmad Ameri

### Contact details

Imam Hossein Hospital  
Department of Radiation Oncology  
Shahid Madani St  
Tehran  
Iran  
1617763141  
+98 (0)21 7755 2056  
A\_Ameri@sbmu.ac.ir

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Benzydamine versus placebo in radiation-induced mucositis in patients with head and neck cancer: a phase II randomised controlled trial

## Acronym

Gorgani II

## Study objectives

Benzydamine can prevent radiation-induced mucositis in head and neck cancer patients.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Imam Hossein Hospital, Department of Radiation Oncology Ethics Committee approved on the 10th July 2009 (ref: 122)

## Study design

Phase II randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Head and neck cancer/mucositis

## Interventions

Patients will be randomised in two groups (placebo and benzydamine). Subjects were encouraged to brush their teeth at least twice daily, floss once daily, rinse as necessary with bland oral rinses (e.g., normal saline, sodium bicarbonate). Commercial mouthwashes (over the counter or prescription), chlorhexidine, or other agents to aid in oral hygiene were prohibited.

Oral rinsing with study treatments was initiated the day before RT and continued for 2 weeks after the end of RT. 15 ml for 2 minutes, 4 - 8 times daily before and during RT, and for 2 weeks after completion of RT. If burning or stinging occurred, dilution of the rinse with water at 1:1 or 1:2 was allowed. All bottles of study rinse were returned each week and the amount returned recorded.

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Benzydamine

**Primary outcome measure**

Reducing mucositis, measured during treatment (from the first day of radiotherapy until one week after termination of radiotherapy)

**Secondary outcome measures**

1. Time to grade III mucositis

2. Time to grade IV mucositis

Measured during treatment (from the first day of radiotherapy until one week after termination of radiotherapy).

**Overall study start date**

10/06/2009

**Completion date**

10/04/2010

**Eligibility****Key inclusion criteria**

1. Male and non-pregnant female subjects aged 18 - 80 years

2. Diagnoses of head and neck malignancy

3. Total external beam radiotherapy (RT) dose of at least 5000 cGy via a megavoltage treatment with either a cobalt-60 or a linear accelerator

4. At least two oral mucosal sites included in the planned RT treatment volume

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50 (25 in each arm)

**Key exclusion criteria**

1. Karnofsky performance status less than 80%
2. Hypersensitivity to benzydamine or typical nonsteroidal anti-inflammatory drugs (NSAIDs)
3. Had taken experimental drugs within 30 days of study start
4. Chronically took steroids, NSAIDs, or other analgesics for other medical conditions

**Date of first enrolment**

10/06/2009

**Date of final enrolment**

10/04/2010

## **Locations**

**Countries of recruitment**

Iran

**Study participating centre**

Imam Hossein Hospital

Tehran

Iran

1617763141

## **Sponsor information**

**Organisation**

Imam Hossein Hospital (Iran)

**Sponsor details**

Department of Radiation Oncology

Shahid Madani St

Tehran

Iran

1617763141

A\_Ameri@sbmu.ac.ir

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/053qhtw56>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Imam Hossein Hospital (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