

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

Submission date 20/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/02/2010	Condition category 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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Imam Hossein Hospital (Iran)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration