Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

evaluation of silymarin effects in prevention and treatment of mucositis induced by radiotherapy of head and neck

Protocol summary

Summary

This study is a prospective, double-blind, randomized Clinical trial to compare the effects of silymarin consumed orally with placebo, on the prevention and treatment of oral mucositis caused by radiation therapy. In this study, 80 patients in the Department of Oncology OMID Hospital School of Medicine, Mashhad, after starting radiation therapy due to tumor diagnosis have been selected based on random numbers have been divided into one of four treatment groups where in one group they supposed to consume usual tablet, in another one, they used placebo tablet, in third group they have been described liquid form containing silymarin and in fourth group, placebo Nanomicell. Patients in the treatment group with description of Livergol 140 mg three tablets daily (produced Goldaro) or three cc of a solution containing Nanomicell form silymarin which contains 140 mg of silymarin per cc. In the placebo group, they used tablets developed by the same factory which looks identical to Livergol and contains all the ingredients, except the active ingredient pharmaceutical, three pills per day. Patients in all four groups for 6 Week (33 to 30 sessions of radiation therapy is active 5 days a week) with a 6 MV linear accelerator radiation therapy will be (dose in each of the four groups varies between 70-50 Gy) to the drug or placebo, in order to prevent mucositis and radiation therapy to determine its efficacy in the treatment of ulcers in patients with oral mucositis caused by radiation therapy. Radiation therapy continue to the end of this location. In addition, examination of patients with tongue blade and flashlight on the first day of radiation therapy, before radiation and subsequent visits every week until the end of the study has been done. If oral lesions based on the standard CTC NCI v.2 and OMAS (oral mucositis assessment scale) to evaluate oral mucositis are used, they have been graded and finally have been compared the criteria used in the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050622132N1**
Registration date: **2015-08-25, 1394/06/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-25, 1394/06/03

Registrant information

Name
Mohammad reza Niazi Moghadam
Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
evaluation of silymarin effects in prevention and treatment of mucositis induced by radiotherapy of head and neck

Public title
evaluation of silymarin effects in prevention and treatment of mucositis induced by radiotherapy of head and neck

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria :age between 18 and 60, Patients treated with radiation therapy in head and neck; Radiation dose : 50-70 G; At least half of Oral cavity in the radiation exposure exclusion criteria:Liver failure(Because of the clearance of drugs) if ALT and AST level be more than two to three times higher than the upper limit normal at the beginning of treatment tgat patient will be excluded; Renal failure:GFR <50 ml / min; Severe infection requiring antibiotic therapy; Corticosteroids; pevious history of radiation therapy; patient unsatisfaction; A history of allergy to silymarin.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Committee for Medical Research Ethics

Street address
Central Organization of University, Daneshgah St, Mashhad, Iran

City
Mashhad - Iran

Postal code

Approval date
2014-10-25, 1393/08/03

Ethics committee reference number
930401

Health conditions studied

1

Description of health condition studied
mucositis

ICD-10 code
K12.3

ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
Oral Mucositis Assessment Scale

Timepoint
The first week after the intervention, after the intervention of the second week, third week after the intervention, after the intervention of the fourth week, the fifth week after the intervention, after six weeks of intervention

Method of measurement
interviews and Observation

2

Description
visual analogue scale

Timepoint
The first week after the intervention, after the intervention of the second week, third week after the intervention, after the intervention of the fourth week, the fifth week after the intervention, after six weeks of intervention

Method of measurement
visual pain scale

Secondary outcomes

1

Description
hepatic transaminase levels

Timepoint
Beginning of the study, the first week, second week, third week, four weeks, five weeks, six weeks

Method of measurement
laboratory

2

Description
serum creatinine level

Timepoint
Beginning of the study, the first week, second week,

third week, four weeks, five weeks, six weeks.

Method of measurement

laboratory

Intervention groups

1

Description

Livergol 140 mg three tablets daily (produced Goldaro), oral, for 6 weeks

Category

Treatment - Drugs

2

Description

placebo of livergol 140mg, three tablet daily, for 6 week, oral

Category

Placebo

3

Description

three mililiter of nano-silimarine syrup (140mg/cc), for 6 weeks, oral

Category

Treatment - Drugs

4

Description

placebo of nano-silimarine syrup, 3cc/day, for 6 weeks, oral

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Sareh Hosseini

Street address

Omid Hospital, Kohsangi St

City

Mashhad

2

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Sareh Hosseini

Street address

Imam Reza hospital, Emam Reza Sq

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

School of Pharmacy, Vakilabad Blvd.

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Pharm D Student

Other areas of specialty/work

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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