Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of reirradiation in disease control and symptom improvement; and urinary, gastrointestinal, cutaneous and soft tissue complications in patients with local recurrence of rectal, cervical and endometrial malignancies

Protocol summary

Study aim
تعیین عوارض و نتایج پرتودرمانی مجدد لگن در بدخیمی های رکتوم، سرویکس و اندومتر

Design
Cohort study

Settings and conduct
Cares will be chosen from patients of Namazi hospital radiotherapy ward during 1401-1402 Patients will be studied that are known case of rectum, cervix and endometrial malignancies that had previous radiotherapy (3D conformal or brachytherapy) and now has local recurrence of disease at pelvis (without distant metastasis) and are not operable.

Participants/Inclusion and exclusion criteria
Local recurrence of rectum, cervix and endometrial malignancies More than 6 month after previous course of radiation Inoperable patients or needs neoadjuvant reirradiation for better resection or adjuvant reirradiation for better control

Intervention groups
patients with rectum, cervix and endometrial cancer with local recurrence at pelvis

Main outcome variables
Urinary complications; dependent variable; based on Common Terminology Criteria for Adverse Events (CTCAE) Version ۵.۰ Gastrointestinal complications; dependent variable; based on Common Terminology Criteria for Adverse Events (CTCAE) Version ۵.۰ Cutaneous and soft tissue complication; dependent variable; based on Common Terminology Criteria for Adverse Events (CTCAE) Version ۵.۰ Symptom control; dependent variable; based on questionnaire Local control; dependent variable; based on imaging (CT scan or MRI) and response evaluation criteria in solid tumors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220130053877N1**
Registration date: **2022-04-12, 1401/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-12, 1401/01/23**
Update count: **0**

Registration date
2022-04-12, 1401/01/23

Registrant information

Name
Saeed Araby aliabad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3647 4320
Email address
araby.saeed69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effectiveness of reirradiation in disease control and symptom improvement; and urinary, gastrointestinal, cutaneous and soft tissue complications in patients with local recurrence of rectal, cervical and endometrial malignancies

Public title
Reirradiation in pelvic malignancies
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Local recurrence of rectum, cervix and endometrial cancer Inoperable patients or needs neoadjuvant reirradiation for better resection or adjuvant reirradiation for better control More than 6 month after previous course of radiation
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Shiraz University of Medical Sciences
Street address
Radiation oncology ward, Namazi hospital, Namazi Square, Karimkhan Zand bleuvard
City
Shiraz
Province
Fars
Postal code
7193613311
Approval date
2022-01-30, 1400/11/10
Ethics committee reference number
582.IR.sums.med.rec.1400

Health conditions studied

1

Description of health condition studied
Local recurrence of rectal cancer in pelvis
ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

2

Description of health condition studied
Local recurrence of cervical cancer in pelvis
ICD-10 code
C53
ICD-10 code description
Malignant neoplasm of cervix uteri

3

Description of health condition studied
Local recurrence of endometrial cancer in pelvis
ICD-10 code
C54.1
ICD-10 code description
Malignant neoplasm of endometrium

Primary outcomes

1

Description
Urinary complications
Timepoint
1 week, 1 month, 3 month & 6 month after last session of reirradiation
Method of measurement
Common Terminology Criteria for Adverse Events (CTCAE) Version ۵.۰

2

Description
Gastrointestinal complications
Timepoint
1 week, 1 month, 3 month & 6 month after last session of reirradiation
Method of measurement
Common Terminology Criteria for Adverse Events (CTCAE) Version ۵.۰

3

Description
Skin and soft tissue complications
Timepoint
1 week, 1 month, 3 month & 6 month after last session of reirradiation
Method of measurement
Common Terminology Criteria for Adverse Events (CTCAE) Version ۵.۰

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Reirradiation for local recurrence of rectal, cervical and endometrial malignancies
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
saeed araby ali abab
Street address
Radiation oncology ward, Namazi hospital, Namazi square, Karimkhan Zand boulevard
City
Shiraz
Province
Fars
Postal code
7193613311
Phone
+98 71 3647 4332
Email
nemazee_inf@sums.ac.ir
Web page address
https://namazi.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpoor
Street address
7th floor, Shiraz University of Medical Sciences building, Karimkhan Zand bleuvard
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3212 2430
Fax
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Saeed Araby aliabad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Namazi square, Namazi hospital, Radiation oncology ward
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araby.saeed69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Saeed Araby aliabad

Position
Resident

Latest degree
Medical doctor

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Person responsible for updating data

Contact

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Shiraz University of Medical Sciences

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Saeed Araby aliabad

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only participant's datas, protocol of study, Informed consent form and report of clinical study can be shared

When the data will become available and for how long
Available 6 month after result publication

To whom data/document is available
No restriction

Under which criteria data/document could be used
For treatment of cancer patients

From where data/document is obtainable
Email: araby.saeed69@gmail.com

What processes are involved for a request to access data/document
After sending email to me

Comments