

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Detecting the SLN by using methylene blue in the primitive stages of cervical cancer

Protocol summary

Summary

The patients affected by cervical cancer (Ib1-IIa stage) who are candidate for radical hysterectomy and lymphadenectomy will enter in this study. Immediately after anesthesia, 4 ml methylene blue 1% concentration will be injected around the tumor. By starting the lymphadenectomy, the colored sentinel lymph nodes-by mentioning their location-will send for pathological evaluation beside the other sentinel lymph nodes. Lymphadenectomy in other areas will be done and they will send for pathological evaluation. According to SLN involvement (positive or negative) and the other sentinel lymph nodes involvement, this coloring test sensitivity and property, beside assessing whether it could be considered as a valuable test for predicting the SLN involvement, will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205069656N1**

Registration date: **2012-06-12, 1391/03/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-06-12, 1391/03/23

Registrant information

Name

Soheila Aminimoghaddam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2280 5193

Email address

s-aminimoghaddam@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Detecting the SLN by using methylene blue in the primitive stages of cervical cancer

Public title

Detecting the SLN by using methylene blue in patients affected by cervical cancer in the primitive stages; who were treated by surgical approaches in gynaecology wards in Baghiatallah Azam and Imam Khomeini hospitals

Purpose

Screening

Inclusion/Exclusion criteria

The patients affected by cervical cancer (Ib1-IIa stage) who are candidate for radical hysterectomy and lymphadenectomy will enter in this study.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 32

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
Tehran University of Medical Sciences Ethics Committee

Street address
Enghelab Sq. Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2011-12-26, 1390/10/05

Ethics committee reference number
41664-13663-30-02-90

Health conditions studied

1

Description of health condition studied
Radical hysterectomy and lymphadenectomy/Cervical cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Biopsy/pathology result

Timepoint
10 days

Method of measurement
Biopsy/Microscope

Secondary outcomes

empty

Intervention groups

1

Description
Dye injection into the SLN

Category
Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center
Gynaecology ward, Firoozgar hospital

Full name of responsible person
Dr. Soheila Aminimoghaddam

Street address

City
Tehran

2

Recruitment center

Name of recruitment center
Oncology ward, Baghiatollahe Azam hospital

Full name of responsible person
Dr. Soheila Aminimoghaddam

Street address

City
Tehran

3

Recruitment center

Name of recruitment center
Oncology ward, Imam Khomeini hospital

Full name of responsible person
Dr. Soheila Aminimoghaddam

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Farnoush Golband

Street address
Tehran University of Medical Sciences, Research center

City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran 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
 Gynecology ward , Firoozgar Hospital, Tehran
 University of Medical Sciences
Full name of responsible person
 Dr. Soheila Aminimoghaddam
Position
 Assistant professor/ Gynecologist
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