

# 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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 Gynecology ward, Firoozgar Hospital, Tehran  
 University of Medical Sciences  
**Full name of responsible person**  
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**Web page address**

## 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