

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effect of consumption kafir probiotic on saliva count of candida albicans in chemotherapy patients

#### Protocol summary

##### Summary

The aim of this study is evaluation the effect of probiotic consumption on count of albicans candida in chemotherapy patients. In this study, single-blind clinical trial, 50 patients as inclusion criteria (Breast Cancer Patients with Cancer of the colon or candidates for chemotherapy, etc.) and exclusion (pregnant women, smokers, etc.) are selected. Patients are randomly divided into two groups. The intervention group Kafir probiotic yogurt drink and the control group are consumed mineral water. Subjects in both groups at certain hours of the day, hundred cc of it are used. In this study, blood and saliva samples are taken five times. At the turn of chemotherapy, blood and saliva samples will be carried out before receiving chemotherapy drugs. Likewise other samples are taken before the next chemotherapy sessions. The last samples from patients are taken at the end of probiotic administration. At the end of consumption albicans Candida are compared in the two groups. The primary outcome of this study, is saliva count of candida albicans.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201506181760N41**

Registration date: **2015-07-14, 1394/04/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-07-14, 1394/04/23

##### Registrant information

##### Name

Nargess Gholizadeh Pasha

##### Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3236 2282

##### Email address

zahra@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

##### Expected recruitment start date

2015-01-21, 1393/11/01

##### Expected recruitment end date

2015-07-23, 1394/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of consumption kafir probiotic on saliva count of candida albicans in chemotherapy patients

##### Public title

Evaluation of effect of consumption kafir probiotic on saliva count of candida albicans in chemotherapy patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Breast Cancer Patients with Cancer of the colon or candidate for chemotherapy; Patients aged

twenty to sixty years with the same chemotherapy regimen  
Exclusion criteria: Patients with a history of chemotherapy and radiation therapy; Patients with atrophic tongue; Anemia; With mucocutaneous disease; The use of partial or full dentures; With a history of oral diseases; People with underlying medical conditions (eg, diabetes, hypertension, etc.); Pregnant women; Smokers; The use of broad-spectrum antibiotics and anti-fungal drugs

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This study is a single-blind clinical trial. How random is simple. Kafir yogurt and mineral water in containers not show the same content container provided by individual coded. The code other than the person is not aware of the contents of the containers coded.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical sciences

**Street address**

Babol University of Medical Sciences, Ganjafroz Avenu

**City**

Babol

**Postal code****Approval date**

2015-01-10, 1393/10/20

**Ethics committee reference number**

5032

**Health conditions studied****1****Description of health condition studied**

Oral candidiasis

**ICD-10 code**

B37

**ICD-10 code description**

Candidiasis

**Primary outcomes****1****Description**

The number of Candida albicans in normal flora

**Timepoint**

Before receiving chemotherapy treatment and at the end of last sampling of the patients taking probiotics

**Method of measurement**

Laboratory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention groups: Probiotic yogurt in this group hundred cc Kafir (manufactured in Iran) at certain hours of the day drink. Kafir yogurt and mineral water in containers not show the same content container are produced by individual coding.

**Category**

Other

**2****Description**

Control groups: Patients in this group hundred ml mineral water every day at a specific time of day to drink.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Martyr Rajai Hospital Babolsar

**Full name of responsible person**

Sahar Latifi

**Street address**

Shahid Rajaei Hospital Babolsar, Shariati Street

**City**

Babolsar

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research and Technology, Babol  
University of Medical Sciences

**Full name of responsible person**

Dr. Ali Bijani

**Street address**

Babol University of Medical Sciences, Ganjafroz Avenue

**City**

Babol

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research and Technology, Babol  
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**

Dental colleges of Babol

**Full name of responsible person**

Sahar Latifi

**Position**

Dental students

**Other areas of specialty/work****Street address**

Dental colleges of Babol, Babol University of Medical  
Sciences, Ganjafroz Avenue

**City**

Babol

**Postal code****Phone**

+98 11 3229 1408

**Fax****Email**

asemoon2012@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Dental colleges of Babol

**Full name of responsible person**

Dr. Mohammad Mehdizadeh

**Position**

Maxillofacial surgery

**Other areas of specialty/work****Street address**

Dental colleges of Babol, Babol University of Medical  
Sciences, Ganjafroz Avenue

**City**

Babol

**Postal code****Phone**

+98 11 3229 1408

**Fax****Email**

Dr.rmohammad@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Nargess Gholizadeh Pasha

**Position**

MSc

**Other areas of specialty/work****Street address**

Babol University of Medical sciences, Ganjafroz  
Avenue

**City**

Babol

**Postal code****Phone****Fax****Email**

ngh\_pa@yahoo.com

**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*