

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation of physical, chemical and rheological properties of chocolate prepared with D-tagatose, galactooligosaccharide and stevia and sensory evaluation of the very chocolate in healthy subjects, and comparing the results to those of conventional chocolate available in the market

#### Protocol summary

##### Summary

The aim of the present study is to come up with an appropriate chocolate formulation, using tagatose, galactooligosaccharide and stevia and evaluation of its physico-chemical, rheological and sensory properties. Sensory evaluation of the present study is a single-blinded trial from which, subjects with a cold will be excluded. 10 panelists will be recruited. The subjects will consume 20 grams of conventional chocolate prepared with 50% sucrose, 30% cocoa butter and 20% cocoa mass. After 10 minutes of interval and rinsing their mouth with a glass of water, panelists will be provided with 20 grams of a chocolate so similar to the conventional type regarding the chemical structure, except that 5% of the total weight is replaced by a mixture of tagatose, galactooligosaccharide and stevia. Special questionnaires evaluating sensorial characteristics of the chocolates including flavor, taste, after taste, mouth feeling and general acceptance of the sample will be filled in instantly by the participants, after consuming each chocolate. Sensory evaluation will be performed just once for each subject.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112205554N4**  
Registration date: **2012-03-24, 1391/01/05**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-03-24, 1391/01/05

#### Registrant information

##### Name

Aziz Homayouni

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1231 3431

##### Email address

homayounia@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

#### Expected recruitment start date

2012-02-14, 1390/11/25

#### Expected recruitment end date

2012-03-15, 1390/12/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of physical, chemical and rheological properties of chocolate prepared with D-tagatose, galactooligosaccharide and stevia and sensory evaluation of the very chocolate in healthy subjects, and comparing the results to those of conventional chocolate available in the market

#### Public title

Effect of D-tagatose, galactooligosaccharide and stevia

on properties of chocolate

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria : not having a cold Exclusion criteria :  
having a cold

### **Age**

From **10 years** old to **70 years** old

### **Gender**

Both

### **Phase**

2-3

### **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)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tabriz University of Medical  
Sciences

##### **Street address**

Golbad Ave

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2012-02-20, 1390/12/01

#### **Ethics committee reference number**

90102

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Healthy subjects

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Acceptance of the sample

#### **Timepoint**

Right after consumption

#### **Method of measurement**

Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

20 grams of conventional chocolate available in the  
market

#### **Category**

Prevention

### 2

#### **Description**

20 grams of chocolate containing 5% tagatose,  
galactooligosachharide and stevia added to achieve  
better texture

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Aziz Homayouni Rad

##### **Street address**

Attar Neyshapoori Avenue, Golgasht Street

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for Research, Tabriz University of  
Medical Sciences

##### **Full name of responsible person**

Mohammadreza Rashidi

##### **Street address**

Golbad Street

##### **City**

Tabriz

**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, Tabriz 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Aziz Homayouni Rad  
**Position**  
Assistant professor/PhD in food science and nutrition  
**Other areas of specialty/work**  
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homayounia@tbzmed.ac.ir  
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### Person responsible for scientific

## inquiries

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**Web page address**

### Person responsible for updating data

#### Contact

## 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*