

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Qualitative properties and sensory evaluation of dietary chocolate milk prepared using stevia sweetener in comparison with the conventional chocolate milk by healthy assessors

#### Protocol summary

##### Summary

Objectives: Type 2 diabetes mellitus (DM), is a disease with a rising prevalence in Iran that its incidence is mainly due to changed diets specially with high levels of sugar and fat. Nowadays there is an increasing tendency to low caloric natural foods. Stevia rebaudiana is a kind of natural sweetener with zero calorie having the sweetness of 300 times or more than that of sugar and on the contrary of artificial sweeteners it doesn't lead to health problems. Because of very few diabetic dairy products in Iran, we sought to assess production of a diabetic chocolate milk prepared using Stevia. We will also use Inulin to enhance texture properties of chocolate milk and meanwhile have a prebiotic in our new functional food. Design: This study will be carried out in 6 treatments with 3 repetitions by Randomized Complete Block Design (RCBD). Stevia will be substitute with sucrose in three portions of sucrose to Stevia; 100:0 (as the control), 50:50 and 0:100. Inulin, in three levels of %2, %4 and %6, will be also added to the treatment using %100 stevia and no sucrose. Some physicochemical, rheological and sensory properties will be determined to investigate the effect of Stevia and Inulin application on quality of chocolate milk. Sensory evaluation will be performed by 8 trained and 8 untrained assessors. Untrained assessors will participate in the acceptance test to determine the acceptance of the new products by ranking scale. To detect the differences through the treatments, discrimination tests will be performed by trained assessors. The participants should be devoid of any kinds of diseases (especially a cold) and should not smoke. A written consent will be obtained from all the subjects prior to the intervention. Conduct and interventions: In every sensory test 250cc of each product will be presented to the assessors who will be unaware of the type of chocolate milk they consume each time. The samples will be taste in the day

of production, after reaching to the refrigerator temperature (4°C). Because of exposing to the pasteurization process during the production procedure, there will be no microbial risk for assessors. Furthermore, inulin and stevia are two substances which are permitted by FDA to be used in food products. At the end, analysis of data will be carried out by ANOVA using SPSS software ver. 16.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201106245554N3**

Registration date: **2011-07-31, 1390/05/09**

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

Last update:

Update count: **0**

##### Registration date

2011-07-31, 1390/05/09

##### 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**

2011-07-21, 1390/04/30

**Expected recruitment end date**

2012-03-18, 1390/12/28

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Qualitative properties and sensory evaluation of dietary chocolate milk prepared using stevia sweetener in comparison with the conventional chocolate milk by healthy assessors

**Public title**

Comparison of some physicochemical, rheological and sensory properties of dietary chocolate milk prepared using stevia with conventional chocolate milk

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

inclusion criteria: not having any diseases (including a cold); not smoking; exclusion criteria: having any diseases (including a cold); smoking

**Age**

From **20 years** old to **40 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **8**

**Randomization (investigator's opinion)**

Randomized

**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**

2011-06-19, 1390/03/29

**Ethics committee reference number**

9018

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

healthy assessors

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

sensory evaluation of the 6 treatments and comparing them

**Timepoint**

Exactly after the consumption of 250 cc of the product

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

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

250 cc of chocolate milk prepared using stevia

**Category**

Prevention

**2****Description**

250 cc of chocolate milk prepared using stevia and inulin

**Category**

Prevention

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Aziz Homayouni Rad

**Street address****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**

Dr. Mohammad Reza Rashidi

**Street address**

Golbad Ave.

**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**

Dr. Aziz Homayouni Rad

**Position**

Assistant Professor, Department of Food Science and Technology

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

Attar Neyshabouri Street, Golgasht Street

**City**

Tabriz

**Postal code**

5166614711

**Phone**

+98 41 1335 7581

**Fax****Email**

Homayounia@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

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

Tabriz university of medical science

**Full name of responsible person**

Dr. Aziz Homayouni Rad

**Position**

Assistant Professor, Department of Food Science and Technology

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

Attar Neyshabouri Street, Golgasht Street

**City**

Tabriz

**Postal code**

5166614711

**Phone**

+98 41 1335 7581

**Fax****Email**

Homayounia@tbzmed.ac.ir

**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*