

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Evaluation of freeze-thawing method in reducing viral load of Cytomegalovirus in the breast milk of preterm infants.

Protocol summary

Summary

Objectives: Evaluation of freeze-thawing method in reducing viral load of Cytomegalovirus in the breast milk of preterm infants; Design: Single arm study, single blind, no placebo. one-centered; Setting and conduct: The breast milk of 78 mothers with preterm infants who were seropositive for CMV, were included in the study, for assessing CMV viral load with PCR . In positive viral loads of CMV, after freezing the milk for 72 hours and then, thawing it, the CMV viral load will be assessed again with PCR. After 2-3 months CMV viral load will be assessed in infants' urine sample by PCR. Major Inclusion criteria: immune mothers to CMV with preterm infants (under 32 weeks) or low birth weight (below 2000 grams); Major Exclusion criteria: Seronegative mothers (IgG-, IgM-); Sample size: 78; Intervention duration: 1 year Intervention: freezing the infected milk with CMV for 72 hours and thawing it before consumption main outcome variables: Assessing CMV viral load in the milk of mothers with preterm infants; Comparing the viral load between the milk of mothers with preterm infants before and after freezing

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310164113N6**

Registration date: **2015-10-05, 1394/07/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-05, 1394/07/13

Registrant information

Name

Mohammad Bagher Hosseini

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

hossainm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of freeze-thawing method in reducing viral load of Cytomegalovirus in the breast milk of preterm infants.

Public title

Evaluation of freezing - thawing method in reducing the CMV(Cytomegalovirus) Viral load in the breast milk of mothers with preterm infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: mothers with preterm infants (under 32 weeks) or low birth weight (below 2000 grams); Mothers who are immune to CMV (IgG+, IgM-); Mothers with acute

CMV infection, based on serologic findings (IgG+,IgM+)
Exclusion criteria: mothers with infants more than 2000 grams or more than 32 weeks of gestation; Seronegative mothers (IgG-,IgM-)

Age

From **1 day** old to **3 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Research and technology deputy, third floor, central building number 2, Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Postal code

Approval date

2015-05-25, 1394/03/04

Ethics committee reference number

tbzmed.rec.1394.165

Health conditions studied

1

Description of health condition studied

Cytomegalovirus

ICD-10 code

B25.9

ICD-10 code description

Cytomegaloviral disease, unspecified

Primary outcomes

1

Description

The Cytomegalovirus I load in milk

Timepoint

Before and after 72 hours of freezing in -20 degree of Celcius

Method of measurement

Using real time PCR(copies/mL)

Secondary outcomes

1

Description

Cytomegalovirus load in infant blood

Timepoint

2 -3 months of age in infants

Method of measurement

Assessing infants' urine samples with real time PCR

Intervention groups

1

Description

Control group: We couldn't choose a control group because of ethical limitations of finding CMV virus in the breast milk of the mothers with preterm infants and not doing any interventions such as freezing.

Category

Prevention

2

Description

Intervention group: Freezing the breast milk at -20°C for 72 hours and then thawing it in refrigerator

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra teaching hospital of Tabriz

Full name of responsible person

Mohammad Bagher Hosseini

Street address

Alzahra teaching hospital, Baghshomal intersect, Artesh 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

Mohammad Bagher Hosseini

Street address

Central building of Tabriz University of Medical Sciences, Golgasht street, Azadi 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**

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Bagher Hosseini MD

Position

Associate professor in Neonatology

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

Pediatric health Research center, Children hospital, Sheshgelan street, Abbasy Ave

City

Tabriz

Postal code**Phone**

+98 41 3526 2265

Fax**Email**

hossainm@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Bagher Hosseini MD

Position

Associate Professor of Neonatology

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

Pediatric health Research center, Children hospital, Sheshgelan street, Abbasy Ave

City

Tabriz

Postal code**Phone**

+98 41 3526 2265

Fax**Email**

hosseini.neo@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Pediatric Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Bagher Hosseini MD

Position

Associate Professor of Neonatology

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

Pediatric health Research center, Children hospital, Sheshgelan street, Abbasy Ave

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+98 41 3526 2265

Fax**Email**

hosseini.neo@gmail.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