

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between 20G and 22G for second trimester amniocentesis in terms of technical aspects and short-term complications

Protocol summary

Summary

Aim of this randomized controlled trial is to comparison between 20G and 22G for second trimester amniocentesis in terms of technical aspects and short-term complications. In this study target population are pregnant women 15 to 21 weeks that refer to Fetal Medicine Unit (FMU) of Alzahra teaching hospital to detect chromosomal abnormalities or genetic disease with amniocentesis. Inclusion criteria: single pregnancy; no history of cervical classic failure, hereditary or non-hereditary coagulation disorders, myoma, major fetal anomalies. By considering $\alpha = 0.05$ and power = 80% and 50% difference in pain intensity difference between two group 200 sample was determined for each group. Amniocentesis will be made with 20 gauge needle in one group and will be made with 22G in the other group. The primary outcome of this study is pain intensity during amniocentesis, which will be measured by VAS (Visual Analog Scale) system. Also, the incidence of spontaneous abortion under 22 weeks, Continuous leakage of amniotic fluid, chorioamnionitis, uterine cramps and vaginal bleeding after the procedure will be studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510037676N3**

Registration date: **2015-10-29, 1394/08/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-29, 1394/08/07

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between 20G and 22G for second trimester amniocentesis in terms of technical aspects and short-term complications

Public title

Comparison between 20G and 22G for amniocentesis complications

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: single pregnancy; no history of cervical classic failure, hereditary or non-hereditary coagulation disorders, myoma, major fetal anomalies. Exclusion criterion: withdrew from continuing the research

Age

No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **400**

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

Tabriz University of Medical Science

Street address

Golgasht Ave

City

Tabriz

Postal code

Approval date

2015-06-29, 1394/04/08

Ethics committee reference number

5/4/3714

Health conditions studied

1

Description of health condition studied

Detect of chromosomal abnormalities

ICD-10 code

Q92.1

ICD-10 code description

تربزومی کروموزومی و موزائیسیم

Primary outcomes

1

Description

Pain intensity

Timepoint

During amniocentesis

Method of measurement

VAS (Visual Analog Scale) system

Secondary outcomes

1

Description

Abortion under 22 weeks

Timepoint

Up to a week after amniocentesis

Method of measurement

During the phone call. The symptoms of bleeding and pain and miscarriage

2

Description

Vaginal bleeding

Timepoint

Up to a week after amniocentesis

Method of measurement

1-Less than menstrual bleeding 2-menstrual bleeding 3-more than menstrual bleeding

3

Description

Continuous leakage of amniotic fluid

Timepoint

After 6 hours of amniocentesis to 1 week after the procedure

Method of measurement

Observation, ultrasound , nitrazine test

4

Description

Chorioamnionitis

Timepoint

Until a week after the procedure

Method of measurement

Uterine tenderness and maternal fever greater than 38°C

5

Description

Uterine cramps

Timepoint

After 6 hours of amniocentesis to 1 week after the procedure

Method of measurement

Uterine contractions felt by the patient

Intervention groups

1

Description

20 gauge needle will be used for Amniocentesis in group

1

Category

Diagnosis

2

Description

22 gauge needle will be used for Amniocentesis in group 2

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital

Full name of responsible person

Barband Sharare

Street address

Baghshomal square

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Research deputy, Tabriz University OF medical Sciences, Golgasht 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

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

Barband Sharare

Position

Medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associated prof of Ob & Gyn, fellowship of perinatology

Other areas of specialty/work

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Barband Sharare

Position

Medical student

Other areas of specialty/work

Street address

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City

Tabriz

Postal code

Phone

00

Fax

Email

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