

Maternal psychological Outcome after Multifetal pregnancy reduction

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON52483

Source

ToetsingOnline

Brief title

MOM study

Condition

- Other condition
- Postpartum and puerperal disorders
- Obstetric and gynaecological therapeutic procedures

Synonym

Multifetal pregnancy reduction

Health condition

Emotioneel welbevinden

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Decision-making process, Multifetal pregnancies, Multifetal pregnancy reduction, Psychological outcome

Outcome measures

Primary outcome

These include the results of the thematic analysis of the interviews, mainly focusing on 1) the factors and considerations that play a role in the decision-making process of multifetal pregnancy reduction, and 2) the emotional aspects and consequences of the decision to or not to perform multifetal pregnancy reduction, during pregnancy and thereafter

Secondary outcome

To assess: 1) How parents look back at the decision of reducing or maintaining their multifetal pregnancy, 2) If and how the decision affected the parents* relationship, 3) The satisfaction with the information that was provided, prior to the decision, 4) The satisfaction with the guidance during the decision-making process and thereafter

Study description

Background summary

Multifetal pregnancies, especially triplets and higher-order multifetal pregnancies, are associated with an increased risk of perinatal and maternal morbidity and mortality. Therefore, all women with higher-order multifetal pregnancies should be counselled for the possibility of multifetal pregnancy

reduction. In the decision-making process to or not to perform multifetal pregnancy reduction the risk of the procedure (i.e. a small chance of miscarriage) has to be balanced against the possible medical complications associated with a multifetal pregnancy. In order to optimize the decision-making process of reducing or maintaining a multifetal pregnancy it is important for clinicians to understand parents* considerations and decisions during this process, and also to provide parents accurate information on the psychological health state shortly after multifetal pregnancy (reduction) as well as in the years thereafter. Therefore, the aim of this study is to increase knowledge on the decision-making process of reducing or maintaining a multifetal pregnancy and to assess the emotional impact of this decision during pregnancy and thereafter. This information can be used by obstetrician-gynaecologists in the future to optimize information for and guidance of parents with multifetal pregnancies, so they can make a well-informed decision on reducing or maintaining their multifetal pregnancy.

Study objective

The primary objectives of this study are 1) to assess the factors and considerations that play a role in the decision-making process of either multifetal pregnancy reduction or maintaining a multifetal pregnancy, and 2) to assess the emotional aspects and consequences of the decision, during pregnancy and thereafter.

Study design

Qualitative cross-sectional study using semi-structured face-to-face in depth interviews

Study burden and risks

Based on the NFU risk classification, we estimate the risk of participating in this study *negligible*. The potential risk of psychological discomfort related to this study is highlighted in the patient information form (PIF). If any of these feelings occur during the study period the participant is asked to either contact the research team or to (anonymously) contact the independent expert. In case of any concerns the psychiatrist in our research team can be consulted for advice. In any case, professional help can be offered. The general practitioner then will be notified. We will pay extra attention on the emotional well-being of women and biological fathers who experienced (severe) pregnancy complications such as loss of their child or children or loss of the entire pregnancy. We hope that participation in this study will offer the possibility to improve processing of the participant*s emotions. All participants will be contacted by telephone within two weeks after their interview to evaluate how they look back on participating in this study. We use this moment to assess for possible psychological distress and if participants

require any further professional care or follow-up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

Mothers: 1) A woman with a history of multifetal pregnancy reduction, from triplet to twin or triplet to singleton from 1 year ago until 6 years ago, 2) A woman with a history of an ongoing triplet pregnancy, counselled for multifetal pregnancy reduction from 1 year ago until 6 years ago . Fathers: 1) A biological father of a triplet pregnancy where counselling for multifetal pregnancy reduction took place from 1 year ago until 6 years ago.

Exclusion criteria

1) Age < 18 years, 2) The procedure of multifetal pregnancy reduction was performed because of a congenitally abnormal fetus, 3) The procedure of multifetal pregnancy reduction was performed because of a serious maternal medical indication, 4) The woman was not counselled for multifetal pregnancy reduction, 5) The woman or biological father does not speak and understand the Dutch language, 6) Objection about the use of data for research was made previously.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	18-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date: 02-03-2022
Application type: Amendment
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74482.029.20