Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

NEONATAL OUTCOMES FOLLOWING METFORMIN FIRST VERSUS INSULIN TREATMENT OF MATERNAL GESTATIONAL DIABETES Mellitus, A RCT

Protocol summary

Study aim
To compare neonatal outcomes following metformin-first versus insulin treatment of maternal gestational diabetes mellitus in a randomized controlled trial

Design
Single center prospective open -label parallel group superiority RCT

Settings and conduct
Maternal Fetal Medicine Department of Obstetrics and Gynaecology Lady Reading Hospital MTI Peshawar

Participants/Inclusion and exclusion criteria
Women aged ≥18 years with a singleton viable pregnancy randomized at 24+0–33+6 weeks with GDM inadequately controlled after 7–14 days of lifestyle intervention and glucose monitoring, and providing written informed consent for neonatal assessment and follow-up Pre-existing or overt diabetes HbA1c ≥6.5%urgent insulin requirement ketosis symptomatic hyperglycemia or fasting glucose 6.0–6.9 mmol/L with significant fetal overgrowth polyhydramnios current glucose lowering medication multiple pregnancy major fetal anomaly or growth restriction hypertension or preeclampsia imminent delivery significant hepatic renal disease acute kidney injury acidosis severe infection dehydration or relevant drug allergy inability to consent or complete follow-up or participation in another interventional trial

Intervention groups
Metformin first treatment titared to tolerance and glucose response with prompt supplemental insulin

Main outcome variables
Neonatal hypoglycemia blood glucose below the prespecified threshold within 48 hours of birth Birth weight large forgestationalage macrosomia respiratory distress NICU admission preterm birth low birth weight Apgar scores 1 and 5 minutesand neonatal death Percentage of fasting and 1hour postprandial glucose readings within targets maternal weight change insulin rescue and dose mode of delivery pre-eclampsia and adverse effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261021071512N1**
Registration date: **2026-10-26, 1405/08/04**
Registration timing: **prospective**

Last update: **2026-10-26, 1405/08/04**
Update count: **0**

Registration date
2026-10-26, 1405/08/04

Registrant information

Name
Hina Niaz
Name of organization / entity
Lady Reading Hospital
Country
Pakistan
Phone
+92 332 9265356
Email address
drhinaniaz11@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-11-01, 1405/08/10

Expected recruitment end date
2027-04-30, 1406/02/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
NEONATAL OUTCOMES FOLLOWING METFORMIN FIRST VERSUS INSULIN TREATMENT OF MATERNAL GESTATIONAL DIABETES Mellitus, A RCT

Public title
A Comparison of Newborn Health Outcomes in Babies Born to Mothers with Gestational Diabetes Treated with Metformin or Insulin

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Age more than or equal to 18 Single viable pregnancy, randomization at 24 to 33 +6 weeks GDM first diagnosed in the current pregnancy Glucose remaining above the study targets after 7 to 14 days of individualised nutrition/ activity advice and monitoring The women must provide written informed consent Willing to receive either strategy and give permission for infant assessments and follow up

Exclusion criteria:
Known pre Gestational type 1 or type 2 Diabetes Overt Diabetes in pregnancy or valid HbA1c more than or equal to 6.5% Urgent need for insulin Ketosis Marked symptomatic hyperglycemia Fasting glucose 6.0 to 6.9 mmol/L accompanied by significant fetal over growth/ polyhydramnios Ongoing glucose lowering medication fir this pregnancy Multiple pregnancy Known major fetal structural or chromosomal anomalies Diagnosed fetal growth restriction Established hypertension or preeclampsia Imminent planned delivery or a condition likely to acquire delivery within 7 days Active significant liver disease Known renal disease or acute kidney injury Acidosis, hypoxia severe infection dehydration or relevant drug allergy Inability to give consent Unresolvable followup

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **560**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible pregnant women diagnosed with gestational diabetes mellitus will be randomly allocated in a 1:1 ratio to either the metformin-first treatment group or the insulin treatment group. A computer-generated random sequence will be used to determine group allocation. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared by an independent person. Randomization will be performed at the individual participant level. No stratification or block randomization will be used.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Lady Reading Hospital Medical Teaching Institute Institutional Review Board

Street address
House 1967 Gulshan Umar colony Gulberg No 2

City
Peshawar

Postal code
25000

Approval date
2026-09-22, 1405/06/31

Ethics committee reference number
577/LRH/MTI

Health conditions studied

1

Description of health condition studied
Gestational Diabetes Mellitus

ICD-10 code
O24.41

ICD-10 code description
Gestational diabetes mellitus in pregnancy

Primary outcomes

1

Description
Neonatal hypoglycemia birthsize prematurity respiratory morbidity NICU mortality maternal weight change insulin rescue delivery mode preeclampsia

Timepoint
24 to 33 weeks

Method of measurement
Laboratory

Secondary outcomes

1

Description
weight, large-for-gestational-age, macrosomia, respiratory distress, NICU admission, preterm birth, low birth weight, Apgar scores (1 and 5 minutes), and neonatal death.
Timepoint
24 weeks antenatal to 28 days post natal
Method of measurement
Laboratory physical assessment stethoscope weight machine

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Lady Reading Hospital
Full name of responsible person
Hina Niaz
Street address
House no 1967 Gulshan Umar colony Gulberg No 2
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Lady Reading Hospital
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Lady Reading Hospital
Full name of responsible person
HINA NIAZ
Position
Fellow Maternal and Fetal Medicine
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
De-identified Individual Participant Data (IPD) including baseline maternal demographics, gestational diabetes clinical metrics, metformin/insulin intervention logs, and primary/secondary neonatal outcomes (e.g., birth weight, neonatal hypoglycemia incidence, NICU admission rates, APGAR scores, gestational age at birth). The study protocol, statistical analysis plan, and informed consent forms will also be included.
When the data will become available and for how long
Data will become available starting 6 months following the official publication of the main study findings in a peer-reviewed journal and will remain accessible for a period of 5 years.
To whom data/document is available
Data will be made available to qualified researchers and clinicians affiliated with academic institutions, university medical centers, or recognized healthcare research organizations who wish to perform secondary data analyses or systematic reviews/meta-analyses.
Under which criteria data/document could be used
Requests will be evaluated for methodologically sound research proposals aimed at improving clinical knowledge on maternal-fetal/neonatal outcomes in gestational diabetes. Requesters must submit a formal research proposal and provide approval from their institution's ethics review board (IRB/ERB). Data must be used strictly for the approved research purpose.
From where data/document is obtainable
Data can be requested directly from the Principal Investigator or the Department of Obstetrics & Gynecology / Pediatrics at Lady Reading Hospital (LRH), Peshawar, Pakistan. Contact Email:drhinaniaz11@yahoo.com
What processes are involved for a request to access data/document
Interested researchers must submit a formal request via email containing: A summary of the scientific rationale and research protocol. Proof of Institutional Review Board (IRB) / Institutional Ethical Review Board (IERB) approval from Lady Reading Hospital or the applicant's institution. A signed Data Use Agreement (DUA) ensuring participant privacy and non-redistribution. The request will be reviewed by the research/steering committee within 4 to 6 weeks. Upon approval, anonymized data files will be shared securely via encrypted digital transfer.
Comments