

Nurse-based management screening in patients with gestational diabetes

Submission date 18/05/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/09/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/09/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Gestational diabetes mellitus (GDM) is an impaired glucose (blood sugar) tolerance with onset or first recognition during pregnancy. If GDM is untreated it can lead to serious complications such as stillbirth. There are normally certain protocols in hospitals on how GDM is dealt with. Usually the management of gestational diabetes patients involves the patient being taken over by the diabetologist from the diagnosis at birth. Researchers have come up with a new protocol. In this new organizational protocol, diabetes counseling with the diabetologist is only foreseen in case of need of insulin (that controls blood sugar levels) therapy. This protocol was compared to the previous one, which instead provided for the presence of the diabetologist both for the first evaluation and the monitoring. With the same clinical outcomes there is an important reduction in the number of visits to the diabetologist. The aim of the present study is to evaluate whether the application of a new organizational protocol for the management of women with gestational diabetes predominantly conducted by a nurse and dietitian can be pursued without affecting the quality of care. The aim of this study is to create a mainly nurse/dietitian-based GDM management protocol to reduce medical examinations without affecting clinical and welfare quality.

Who can participate?

Pregnant women aged 18 to 45 who do not have type 1 or type 2 diabetes.

What does the study involve?

Participants are allocated to two groups. The first group is based on a traditional protocol with patients' blood glucose constantly checked by a Diabetologist. In the second structured group, participants are only referred to a Diabetologist if they required insulin therapy. Participants are followed up to compare the two protocols and see how the blood glucose is monitored and if the number of medical visits participants attends.

What are the possible benefits and risks of participating?

Participants may benefit from better monitoring. There are no direct risks with participating.

Where is the study run from?

Departements of UOC Malattie Metaboliche E Uo Ostetricia E Ginecologia (Italy)

When is the study starting and how long is it expected to run for?
January 2013 to December 2016

Who is funding the study?
Aulss 2 Marca Trevigiana distretto di Treviso (Italy)

Who is the main contact?
Dr Agostino Paccagnella

Contact information

Type(s)
Scientific

Contact name
Dr Agostino Paccagnella

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

-

Study information

Scientific Title
Can a nurse-based management screening ensure adequate outcomes in patients with gestational diabetes? A comparison of two organizational models

Study objectives
The aim of this study is to create a mainly nurse/dietitian-based GDM management protocol and evaluate whether the clinical results of blood glucose monitoring differed between the two groups involved.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval needed since the protocol has been approved by health management

Study design

Interventional single-centre randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet marialisa.marcon@aulss2.veneto.it

Health condition(s) or problem(s) studied

Gestational diabetes

Interventions

Participant are not randomised since the control group is the group of patients before the protocol. The duration of intervention is the pregnancy period and starts at the diagnosis moment and finishes with the delivery.

The study does not need randomization since the measure is not taken on two different therapies but on two different organizational protocols P1 and P2, whereas the same therapy was used (the only pharmacological therapy involved was insulin) with the same assessment of blood glucose data.

Two different organizational protocols were analysed: The first group of patients was based on a traditional protocol (P1: 230 pts) with patients' blood glucose constantly checked by a Diabetologist. In the second group P2 was applied (P2: 220 pts), and patients were only referred to a Diabetologist if they required insulin therapy.

Organisational Protocol 1 (P1): for this protocol, the Diabetologist manages the entire process even if the patient does not require insulin therapy. Therefore, a nurse and a dietitian, if required, work together under the guidance of a Diabetologist.

Organizational Protocol 2 (P2): for this protocol, the Diabetologist intervenes only if the patient requires insulin therapy.

Total duration of the study is 2 and a half years.

Participants are invited, as described in the protocol, to do a Glucose Tolerance Test (GTT) after 12 weeks after delivery and to show results to their primary care physician. The primary care physician evaluates the need to send the person back to the diabetologist.

Intervention Type

Behavioural

Primary outcome measure

Hypoglycemia is measured using their personal glucose monitor when they feel symptoms, as instructed.

Secondary outcome measures

Number of medical visits is measured using patient number of recorded accesses in the Hospital booking system.

Overall study start date

12/01/2013

Completion date

31/12/2016

Eligibility**Key inclusion criteria**

1. Not have type 1 or type 2 diabetes before becoming pregnant
2. Have balanced food habits (50-60% carbohydrates; 10-15% protein; 20-25% fats) based on a Mediterranean-style diet
3. Have a pre-pregnancy BMI of between 18 and 35 kg/m²
4. Not having an eating disorder or by any type of prior or current psychiatric illness
5. Not having a heart, kidney or liver disease, thrombophilic diathesis or any other already diagnosed chronic disease (e.g. hereditary dyslipdemia, hypertension resistant to treatment with drugs, gout, etc.) before becoming pregnant
6. Not having pre-eclampsia during a previous pregnancy
7. Not having a history of recurrent fetal loss
8. Not having cancer (current or previous)
9. Not expecting twins
10. Aged between 18-45

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

230+220

Key exclusion criteria

1. Morphological ultrasound scan showed evidence of a fetal malformation or soft markers for chromosomal abnormality
2. Invasive diagnosis (chorionic villus sampling or amniocentesis) showed fetal chromosomal abnormality

Date of first enrolment

15/10/2013

Date of final enrolment

15/03/2016

Locations**Countries of recruitment**

Italy

Study participating centre

Departements Of UOC Malattie Metaboliche E Uo Ostetricia E Ginecologia

Ospedale Regionale Ca' Foncello

Via Ospedale

Treviso

Italy

31100

Sponsor information**Organisation**

Aulss 2 Marca Trevigiana distretto di Treviso

Sponsor details

Piazzale Ospedale 1

Treviso

Italy

31100

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00vj45j81>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Aulss 2 Marca Trevigiana distretto di Treviso

Results and Publications

Publication and dissemination plan

The study is ready to be published and the protocol has been approved and is now in use in the Treviso Hospital.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Maria Lisa Marcon from marialisa.marcon@aulss2.veneto.it.

IPD sharing plan summary

Available on request