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# Nurse-based management screening in patients with gestational diabetes

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 18/05/2017 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 21/09/2017 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 21/09/2017 | Nutritional, Metabolic, Endocrine | [ ] 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 dietician 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

### Protocol serial number
-

# 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

## Primary study design
Interventional

## Study design
Interventional single-centre randomised controlled study

## Study type(s)
Screening

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

## Key secondary outcome(s)
Number of medical visits is measured using patient number of recorded accesses in the Hospital booking system.

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
45 Years

### Sex
Female

### 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

### ROR
https://ror.org/00vj45j81

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Aulss 2 Marca Trevigiana distretto di Treviso

## Results and Publications

### 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