ISRCTN61793947 https://doi.org/10.1186/ISRCTN61793947

The PREDG study: testing whether an educational intervention can prevent excess weight gain during pregnancy

Submission date
29/11/2018

Recruitment status
No longer recruiting

Registration date
10/12/2018

Overall study status
Completed

Last Edited
20/07/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
The objective of the present project is to validate the effect of an educational intervention to prevent an excess of gestational weight gain in women with obesity. Excessive gestational weight gain is associated with gestational hypertension, preeclampsian, cesarean section and large birth weight. After pregnancy, gestational weight gain is the main cause of postpartum obesity.

Who can participate?
Women with obesity previous to pregnancy can participate in the study

What does the study involve?
The study involves education on diet and physical activity, information about an adequate gestational weight gain and biochemical and physical specific measurements.

What are the possible benefits and risks of participating?
The possible benefits of the study are obtaining an adequate gestational weight gain and, consequently, reducing pregnancy complications such as hypertension or diabetes.

Whre is the study run from?
Hospital Universitario La Paz, Madrid

When is the study starting and how long is it expected to run for?
November 2018 to June 2022

Who is funding the study?
Fundación Investigación Biomédica Hospital Universitario La Paz (FIBHULP)

Who is the main contact?
Dr Beatriz Barquiel
beatriz.barquiel@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Beatriz Barquiel

Contact details
Ps. Castellana 261
Madrid
Spain
28046

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FIBHULP PI-1980

Study information

Scientific Title
The PREDG study: a randomised controlled trial testing whether an educational intervention can prevent gestational weight gain in obese women

Acronym
PREDG

Study objectives
An intervention consisting of dietetic education, physical activity and information of women with obesity may be useful to prevent excess gestational weight gain. Consequently, pregnancy complications and pospartum weight retention may be reduced.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité Ético HULP, 06/09/2018, ref. FIBHULP PI-1980.

Study design
Interventional, randomized controlled trial, single-centre, single blind

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gestational weight gain in obese women

Interventions
The randomisation will be automatically generated by a informatic program that assigns an random number to consecutive patients. The intervention arm will have an educational session about an adequate diet and physical activity. Diet will be calculated for the initial BMI, physical activity and pregnancy specific necessities. Both arms will receive information about an adequate gestational weight gain. Both arms will have biochemical determinations: basic, lipid profile, thyroid hormones, body impedance and weight and waist measurement. Follow up will continue for 6 months after delivery.

Intervention Type
Behavioural

Primary outcome measure
Gestational weight gain will be measured using weight (kg) in each monthly visit minus weight before pregnancy.

Secondary outcome measures
1. Pregnancy complications:
1.1. Gestational hypertension as arterial pressure >= 140 and/or 90 mmHg confirmed twice
1.2. Gestational diabetes as defined by NDDG criteria
1.3. Preterm birth as birth before 37 weeks of pregnancy
1.4. Cesarean section as rate of cesarean section
1.5. Macrosomia as neonatal birthweight >= 4 kg
1.6. Small as neonatal birthweight < 10th percentile for gestational age and sex
2. Postpartum weight retention as weight 6 months postpartum minus prepregnancy weight (kg).

Overall study start date
29/11/2018

Completion date

17/06/2022

Eligibility

Key inclusion criteria
1. BMI ≥ 30 kg/m2 prior to becoming pregnant

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
190

Total final enrolment
210

Key exclusion criteria
1. Treatment with an effect on body weight (fluoxetina, orlistat, metformina, GLP-1 agonists, pioglitazone)
2. Illness with organic deterioration (HIV disease, kidney or hepatic advanced insufficiency, cancer)
3. Invalidating mental disease
4. Participants of other study
5. Other criteria considered by the investigator

Date of first enrolment
02/01/2019

Date of final enrolment
07/09/2021

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario La Paz
Ps Castellana 261
Madrid
Spain
28046

Sponsor information

Organisation
Fundación Investigación Biomédica Hospital Universitario La Paz (FIBHULP)

Sponsor details
Ps Castellana 261
Madrid
Spain
28046

Sponsor type
Hospital/treatment centre

Website
idipaz.es

ROR
https://ror.org/01s1q0w69

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for Biomedical Research of La Paz University Hospital

Results and Publications

Publication and dissemination plan
Results on primary and secondary outcomes of the trial will be presented at national and international conferences and published in Endocrinology journals with an impact factor.

Intention to publish date
30/12/2022

Individual participant data (IPD) sharing plan
The available data collected will be available on request for statistical analyses from Dr Beatriz Barquiel (beatriz.barquiel@gmail.com). All participants gave their written informed consent.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/07/2023	20/07/2023	Yes	No