

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/12/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/07/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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, preeclampsia, 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.

Where 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 postpartum 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 < 10 th 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 \geq 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 (fluoxetine, 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