

Metformin Pharmacokinetics in young girls

Submission date 03/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/08/2012	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PIC-72-10

Study information

Scientific Title

Pharmacokinetics of Metformin at age 9

Acronym

MPK

Study objectives

To ascertain whether the pharmacokinetic parameters after oral metformin administration in young children are comparable to those in adults

Ethics approval required

Old ethics approval format

Ethics approval(s)

Review Board Hospital Sant Joan de Deu, approved on 10th November 2010

Study design

Randomised controlled trial

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

Health condition(s) or problem(s) studied

Advanced puberty

Interventions

The patients were sampled after being admitted to the hospital, every 45 minutes for 3 hours and then 4, 6, 8, 10 and 12 hours after metformin intake, 850 mg/d.

The girls were started on metformin at a mean age of 9 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Height velocity: according to local reference curves: Ferrández-Longás A, Mayayo E, Labarta JI, Bagué L, Puga B, Rueda C, Ruiz-Echarri M, Labena C. Estudio longitudinal de crecimiento y

desarrollo. Centro Andrea Prader. Zaragoza 1980-2002. In ERGON, ed. Patrones de crecimiento y desarrollo en España. Atlas de gráficas y tablas., pp 61-115. Madrid: 2004

2. Pubertal status: according to Tanner standards (Marshall WA, Tanner JM. Variations in the pattern of pubertal changes in girls. Arch Dis Child 1969; 44:291-303)

Secondary outcome measures

1. Bone age: according to Greulich & Pyle
2. Uterine and ovarian size: as measured by ultrasound and according to: Griffin IJ, Cole TJ, Duncan KA, Hollman AS, Donaldson MDC. Pelvic ultrasound measurements in normal girls. Acta Paediatr 1995; 84:536-543

Overall study start date

03/03/2011

Completion date

12/03/2011

Eligibility

Key inclusion criteria

The study population consisted of 6 non-obese, Caucasian girls receiving metformin (850 mg/d at dinner time) after a history of low-birthweight (Z-score ≤ -1.5 for gestational age) and early-normal puberty (onset of Tanner breast stage 2 at age 8 yr; increase of uterine and ovarian size by ultrasound; pubertal gonadotropin response to GnRH agonist).

Participant type(s)

Patient

Age group

Child

Sex

Female

Target number of participants

6

Key exclusion criteria

1. A family or personal history of diabetes mellitus
2. A history of precocious pubarche or the presence of other signs of androgen excess
3. Evidence for thyroid dysfunction or glucose intolerance
4. Intake of medications known to affect gonadal function or carbohydrate metabolism.

Date of first enrolment

03/03/2011

Date of final enrolment

12/03/2011

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Sant Joan de Deu, University of Barcelona

Esplugues, Barcelona

Spain

08950

Sponsor information

Organisation

Hospital Sant Joan de Déu, University of Barcelona (Spain)

Sponsor details

Hospital Sant Joan de Deu, Univeristy of Barcelona

c/o Lourdes Ibañez

Esplugues, Barcelona

Spain

08950

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/001jx2139>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Sant Joan de Déu, University of Barcelona (Spain)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011		Yes	No