

# Metformin Pharmacokinetics in young girls

<b>Submission date</b> 03/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/08/2012	<b>Condition category</b> 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

Prof Lourdes Ibañez

### Contact details

Hospital Sant Joan de Deu, University of Barcelona  
Esplugues, Barcelona  
Spain  
08950

## 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  $\leq$  -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?
<a href="#">Results article</a>	results	01/11/2011		Yes	No