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To determine if cardiovascular risk indices including postprandial hypertriglyceridaemia are modified favourably by nicotinic acid (niacin) in patients with polycystic ovary syndrome (PCOS)

Submission date
05/02/2010

Recruitment status
No longer recruiting

Registration date
10/03/2010

Overall study status
Completed

Last Edited
13/02/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stephen Atkin

Contact details
Department of Diabetes, Endocrinology and Metabolism
Hull York Medical School
Michael White Diabetes Centre
Hull Royal Infirmary
Hull
United Kingdom
HU3 2RW
+44 (0)1482 675 365
stephen.atkin@hyms.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT01118598

Study information

Scientific Title
To determine if cardiovascular risk indices including postprandial hypertriglyceridaemia are modified favourably by nicotinic acid (niacin) in patients with polycystic ovary syndrome (PCOS): a randomised double-blind placebo-controlled parallel study

Study objectives
Niacin will improve postprandial hyperlipidaemia and cardiovascular risks indices via its lipid lowering as well as via pleiotrophic effects in patients with polycystic ovary syndrome (PCOS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (East) Research Ethics Committee, 21/01/2010, ref: 09/H1306/103

Primary study design
Interventional

Study design
Single-centre randomised double-blind placebo-controlled parallel trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Polycystic ovary syndrome

Interventions
Patients will be allocated as 1:1 ratio to the intervention group and the placebo group. For the first 4 weeks, participants will take orally either one tablet of nicotinic acid 1000 mg/laropiprant 20 mg (Tredaptive®) or one tablet of placebo per day. If patient tolerates it, the dose will be increased to either two tablets of nicotinic acid 1000 mg/laropiprant 20 mg (Tredaptive®) or two tablets of placebo per day from week 5 to week 12.

Total duration of treatment is 12 weeks and total duration of follow-up is up to 2 weeks after the end of intervention.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Niacin, laropiprant (Tredaptive®)

Primary outcome(s)

To determine if the dyslipidaemic cardiovascular risk indices including postprandial hypertriglyceridaemia are reversed favourably by nicotinic acid (niacin) therapy. Blood tests will be done at baseline, at week 5 and at week 9 and at the completion of the intervention for both groups.

Key secondary outcome(s)
1. To determine the effect of nicotinic acid on insulin resistance and other markers of cardiovascular risk such as high sensitivity c-reactive protein (hsCRP)
2. To determine the effect of nicotinic acid on endothelial function

Blood tests will be done at baseline, at week 5 and at week 9 and at the completion of the intervention for both groups. Endothelial function test will be done at baseline and at the end of the study.

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Females aged between 18 - 50 years
2. Has polycystic ovary syndrome diagnosed according to Rotterdam consensus statement (to meet two out of three criteria after exclusion of other endocrine disorders):
2.1. Patient has oligomenorrhoea (less than nine cycles per year)/anovulation
2.2. Patient has evidence of clinical/biochemical hyperandrogenism
2.3. Patient has polycystic ovaries on trans-vaginal ultrasound

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Pregnancy/trying to conceive/breastfeeding
2. History of cardiovascular, renal, hepatic and active thyroid disease
3. History of gout
4. History of alcohol abuse
5. History of diabetes
6. History of allergy to nicotinic acid/laropiprant or food
7. History of bleeding disorders/active peptic ulcers

8. Patient on antihypertensive medications
9. Patient on anticoagulants
10. Patient on any hormonal replacement or oral contraceptive pills or cholesterol-lowering agents
11. History of smoking more than 15 pack year
12. Unwilling for GP to be informed

Date of first enrolment
01/04/2010

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Diabetes, Endocrinology and Metabolism
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospital NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Hull and East Yorkshire Hospital NHS Trust (UK) - Research and Development Department

Funder Name
Merck, Sharp & Dohme Corp. (UK) - supplies study medicine (Tredaptive® and placebo)

Results and Publications

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	01/06/2014		Yes	No
HRA research summary			28/06/2023	No	No