ISRCTN81902209 https://doi.org/10.1186/ISRCTN81902209

Are early and late cardiovascular risk markers in women with polycystic ovary syndrome (PCOS) increased with concomitant non-alcoholic steatohepatitis (NASH) and can this be modified with exenatide?

Submission date	Recruitment status
27/04/2009	No longer recruiting
Registration date	**Overall study status**
13/05/2009	Completed
Last Edited	**Condition category**
26/04/2019	Nutritional, Metabolic, Endocrine

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R0794

Study information

Scientific Title
Are early and late cardiovascular risk markers in women with polycystic ovary syndrome (PCOS) increased with concomitant non-alcoholic steatohepatitis (NASH) and can this be modified with exenatide?: An interventional open parallel single-centre trial

Acronym
PCOS NASH 2009

Study objectives
Early and late cardiovascular risk markers are exaggerated in women with both polycystic ovary syndrome (PCOS) and non-alcoholic steatohepatitis (NASH) compared to either condition alone, and these can be modified by therapy reflected in an improvement in endothelial dysfunction, fibrin clot structure and function and an improvement in inflammation histologically.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds East Research Ethics Committee, 09/03/2009, ref: 09/H1306/9

Study design
Interventional open parallel single-centre trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Polycystic ovary syndrome, non-alcoholic steatohepatitis

Interventions

Twelve patients will be recruited for each of the three groups: 1) PCOS only, 2) NASH only and 3) PCOS with NASH (total n = 36).

Exenatide 5 mcg subcutaneously (sc) twice a day (bd) for 1 month then exenatide 10 mcg sc bd for 3 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Exenatide

Primary outcome measure
1. To show that the combination of PCOS and NASH significantly amplifies cardiovascular risk markers compared to either PCOS or NASH alone
2. To show that intervention with exenatide significantly improves insulin resistance (an adverse cardiovascular risk marker)

All primary and secondary outcomes will be assessed in September 2010.

Secondary outcome measures
1. To show that intervention with exenatide significantly improves endothelial function (Early manifestation of cardiovascular disease) in subjects with PCOS and NASH
2. To determine if exenatide therapy significantly improves fibrin clot structure and function (Late manifestation of cardiovascular disease) in subjects with PCOS and NASH
3. To determine if exenatide is effective in reducing steatohepatitis by Fibroscan® and reduces the markers of liver fibrosis

All primary and secondary outcomes will be assessed in September 2010.

Overall study start date
01/05/2009

Completion date
30/09/2010

Eligibility

Key inclusion criteria
For PCOS:
1. Polycystic ovary syndrome (defined by the Rotterdam criteria as 2 out of 3 of:
1.1. Oligo/anovulation
1.2. Clinical or biochemical evidence of hirsuitism, and/or
1.3. Polycystic ovaries on ultrasound
2. Raised alanine aminotransferase (ALT)
3. Female, age 16-45 years

For NASH:
1. Patients with confirmed NASH
2. Female
3. Age 16-45 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
36

Total final enrolment
20

Key exclusion criteria
1. Ketoacidosis
2. Severe gastrointestinal disease
3. Type 2 diabetes
4. Hypothyroidism
5. Subjects taking regular prescribed medication
6. Not using a reliable method on contraception (eg barrier/oral contraceptive pill)
7. Patients not allowing disclosure to their GP's
8. History of pancreatitis
9. Chronic renal failure (creatinine clearance less than 60 ml/min or plasma creatinine >150 umol /L)
10. Pregnancy or breastfeeding women
11. Liver function tests >300% reference range normal (e.g., ALT >90 u/mL)
12. Acute conditions with the potential to alter renal function such as:
12.1. Dehydration
12.2. Severe infection
12.3. Shock
12.4. Intravascular administration of iodinated contrast

Date of first enrolment
01/05/2009

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HS Brocklehurst Building
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Daisy Building
Castle Hill Hospital
Cottingham
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
Diabetes Endowment Fund, University of Hull (UK)

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	02/04/2019	26/04/2019	Yes	No
HRA research summary			28/06/2023	No	No