

Purified fatty acids for endometriosis clinical trial

Submission date 01/05/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 30/05/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/06/2023	Condition category Urological and Genital Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Endometriosis is a common condition where tissue that behaves like the lining of the womb (endometrium) is found in other parts of the body. It affects 6-10% of women and causes severe pelvic pain. Endometriosis can be treated surgically or medically. However, symptoms often come back after surgery and the currently available medical treatments are hormones which have undesirable side effects and are contraceptive. Omega-3 purified fatty acid (PUFA) supplements may reduce endometriosis-associated pain, have minimal side effects and no effects on fertility. The aim of this small study is to assess the feasibility of conducting a larger study of PUFA for endometriosis-associated pain.

Who can participate?

Patients aged 18-50 with endometriosis

What does the study involve?

Participants are randomly allocated to receive soft gelatin capsules containing either omega-3 purified fatty acids (fish oil) or olive oil, and are advised to take two capsules per day, one in the morning and one in the evening for 8 weeks. Pain is measured at the start and end of the study and blood samples are collected to measure fatty acid levels.

What are the possible benefits and risks of participating?

PUFAs are a dietary supplement and may reduce endometriosis-associated pain. They have minimal side effects and no effects on fertility.

Where is the study run from?

Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?

October 2013 to May 2017

Who is funding the study?

University of Edinburgh (UK)

Who is the main contact?

1. Mrs Ann Doust (public)
ann.doust@ed.ac.uk
2. Prof. Andrew Horne (scientific)

Contact information

Type(s)

Public

Contact name

Mrs Ann Doust

Contact details

University of Edinburgh
51 Little France Crescent
Edinburgh Eh16 4SA
Edinburgh
United Kingdom
EH16 4SA
+44 (0)131 242 9492
ann.doust@ed.ac.uk

Type(s)

Scientific

Contact name

Prof Andrew Horne

Contact details

QMRI
47 Little France Crescent
Edinburgh
United Kingdom
EH16 4TJ

Additional identifiers

Clinical Trials Information System (CTIS)

2013-004938-15

Protocol serial number

Version 4

Study information

Scientific Title

PurFECT: PURified Fatty acids for Endometriosis Clinical Trial: a randomised controlled trial

Acronym

PurFECT

Study objectives

Endometriosis (womb lining outside the womb) affects 6-10% of women and is associated with debilitating chronic pelvic pain. It costs the UK >£2.8 billion per year in loss of productivity. Endometriosis is managed surgically or medically. However, ~75% symptoms recur after surgery and available medical treatments ('anti-hormones') have undesirable side effects and are contraceptive. Omega-3 purified fatty acids (PUFA) have been shown in animal models to reduce factors that are thought to lead to endometriosis-associated pain, have minimal side effects and no effects on fertility. The trialists plan to perform a feasibility study to inform planning of a future multicentre trial to evaluate the efficacy of PUFA in the management of endometriosis-associated pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Scotland Research Ethics Committee 01, 02/02/2016, ref: 16/SS/0010

Primary study design

Interventional

Study design

Randomised controlled double-blind feasibility study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Endometriosis-related pain

Interventions

Participants are randomised to receive either omega-3 purified fatty acids (fish oil) or olive oil soft gelatin (placebo) capsules, with a dose of 1000 mg each, and advised to take two capsules per day, one in the morning and one in the evening for 8 weeks. The outcomes are measured at baseline and at the end of the study (i.e., 8 weeks).

Intervention Type

Supplement

Primary outcome(s)

1. The proportion of screened women who are eligible for the trial
2. The proportion of eligible patients randomised into the study
3. The proportion of randomised patients who take the supplement and complete questionnaires at final follow up

The outcomes will be measured at baseline and at the end of the study (i.e., 8 weeks).

Key secondary outcome(s)

The remaining outcomes will be used to refine the research methodology of a future large RCT:

1. Pain, measured using the Numerical Rating Score (NRS) collected via text message during the screening phase (-1 to -4 weeks) and last 4 weeks (weeks 5-8) of the treatment phase
2. Eicosapentaenoic acid, arachidonic acid and docosahexaenoic acid concentrations measured from peripheral venous blood samples at baseline and 8 weeks
3. Quality of life, measured using SF-12 at baseline and 8 weeks
4. Pain, measured using the Brief Pain Inventory (BPI) at baseline and 8 weeks
5. Pain catastrophizing, measured using the Pain Catastrophising Questionnaire (PCQ) at baseline and 8 weeks
5. Pain, measures using the PainDETECT™ questionnaire at baseline and 8 weeks
6. Sexual activity, measured using the Sexual Activity Questionnaire (SAQ) at baseline and 8 weeks
7. Fatigue, measured using the Brief Fatigue Inventory (BFI) at baseline and 8 weeks
8. General health, measures using the General Health Questionnaire -12 (GHQ-12) at baseline and 8 weeks
9. Work and productivity activity impairment, measured using the Work and Productivity Activity Impairment Questionnaire- Specific Health Problem version 2.0 (WPAI-SHP) at baseline and 8 weeks
10. Acceptability of proposed methods of recruitment, randomisation, treatments and questionnaires, measured using a questionnaire at 8 weeks

Completion date

01/03/2018

Eligibility

Key inclusion criteria

1. Aged 18-50 years
2. Known endometriosis diagnosed from previous laparoscopy
3. Pain of at least 3 months duration located in the true pelvis
4. Worst pain score ≥ 4 over 4 weeks as measured by Numerical Rating Score (NRS)
5. Ability to provide informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Female

Total final enrolment

33

Key exclusion criteria

1. Unable to take/allergic to fish/PUFA/peanuts/soyabean
2. Insulin dependent diabetes
3. Pregnant
4. Taking contraindicated medications (anticoagulants)
5. Breastfeeding

Date of first enrolment

30/06/2016

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Royal Infirmary of Edinburgh

51 Little France Crescent

Edinburgh

United Kingdom

EH16 4SA

Sponsor information

Organisation

University of Edinburgh and NHS Lothian

ROR

<https://ror.org/03q82t418>

Funder(s)

Funder type

University/education

Funder Name

University Of Edinburgh

Alternative Name(s)

Universitas Academica Edinburgensis, Oilthigh Dhùn Èideann, The University of Edinburgh, University of Edinburgh in United Kingdom, Edin, Tounis College, King James' College, Athens of the North, ED, Edin

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/01/2020	20/01/2020	Yes	No
Protocol article	protocol	01/12/2018		Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	25/01/2016	14/06/2023	No	No