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Myoinositol in adolescent polycystic ovary syndrome

Submission date
15/05/2026

Recruitment status
Not yet recruiting

Registration date
19/05/2026

Overall study status
Ongoing

Last Edited
20/05/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Polycystic Ovary Syndrome (PCOS) is a common hormonal condition that affects many teenage girls. It can cause irregular periods, acne, excess hair growth, and emotional distress. PCOS also increases the risk of long-term health problems like diabetes and heart disease. Current treatments often involve hormonal medications, which some young people and families are reluctant to use due to side effects or cultural concerns. This study, called the MAP Trial, will test whether a natural food supplement called myoinositol could be a helpful alternative. Myoinositol has shown promise in adults with PCOS, but it hasn't been properly studied in teenagers. The MAP Trial is a feasibility study, which means it won't test how well the supplement works just yet – it will check whether a larger trial is possible.

Who can participate?
Girls aged 12–19 years with confirmed PCOS from six NHS hospitals in England (Birmingham, Liverpool, Norwich, and Bristol)

What does the study involve?
Participants will be randomly assigned to take either myoinositol or a placebo (inactive tablet) for 6 months, along with lifestyle advice. We will monitor how many girls agree to take part, how well they stick to the treatment, and how easy it is to collect the necessary data. The study will collect information about symptoms, quality of life, and routine blood tests over three routine appointments. We will also interview some participants and their parents to understand their experiences and views. This will help us improve the design of a future trial.

What are the possible benefits and risks of participating?
Participants may feel better with the treatment. Even if it doesn't help you directly, what we learn might help other teenagers with PCOS in the future. The main effort will be completing the questionnaires, which take about 10–15 minutes.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
July 2026 to October 2027

Who is funding the study?
Action Medical Research for Children (UK)

Who is the main contact?
mapstudy@contacts.bham.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Pallavi Latthe

ORCID ID
https://orcid.org/0000-0003-0529-0409

Contact details
Birmingham Women's Hospital, Mindelsohn Way, Edgbaston
Birmingham
United Kingdom
B15 2TG
+44 (0)121 472 1377
platthe@nhs.net

Type(s)
Public

Contact name
Mrs Rachel Iles

Contact details
Institute Translational Medicine, Heritage Building, Queen Elizabeth Hospital, Edgbaston
Birmingham
United Kingdom
B15 2TH
+44 (0)1213715339
r.iles@bham.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
362931

Central Portfolio Management System (CPMS)
63107

Study information

Scientific Title
Myoinositol in adolescent polycystic ovary syndrome – a trial to evaluate the feasibility of a substantive trial

Acronym
MAP

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/05/2026, North West Greater Manchester West Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8057; gmwest.rec@hra.nhs.uk), ref: 26/NW/0108

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Device feasibility, Health services research, Supportive care

Study type(s)

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

Interventions
Myoinositol 2 g BD (twice a day) or placebo for 6 months

Participants are randomised by the REDCap database using a 1:1 allocation ratio (myoinositol vs placebo). A minimisation algorithm is used within REDCap to ensure balance in site, age (≥16 and <16 years), and weight (≥ or <95th BMI centile for age). A random element is also included to avoid predictability.

Intervention Type
Supplement

Primary outcome(s)
1. Adherence rates measured using participant questionnaires at 3 and 6 months

2. Completion rates of proposed primary outcome measure measured using participant questionnaires at 6 months

3. Acceptability of outcome measures (patient-reported outcome measures [PROMs] identified included excessive body and facial hair, emotional wellbeing, mood and self-esteem, body image, and weight-related concerns) measured using participant questionnaires at baseline, 3 and 6 months

4. Participants' and parental perspectives (disease literacy: their understanding of the condition, its progress and the rationale for treatment; treatment expectations: what they hope to achieve through the intervention [e.g. symptom relief, long term cure]; determinants of study engagement [identifying specific facilitators and barriers to]: recruitment: factors influencing the initial decision to enrol; adherence: challenges or supports in following the treatment regimen; monitoring and data collection; retention: motivations or obstacles to staying in the study until completion) measured using qualitative interviews at 6 months

Key secondary outcome(s))
The study will inform whether a larger RCT can be realistically undertaken and identify potential barriers to its successful completion by assessing the following after patient recruitment has ended:
1. Robustness of data collection processes
2. Proportion of eligible patients screened
3. Proportion of eligible patients randomised
4. Data to inform sample size calculation for main trial
5. Support required for successful recruitment

Completion date
29/10/2027

Eligibility

Key inclusion criteria
1. Age 12-19 years
2. Confirmed diagnosis of adolescent PCOS based on international consensus criteria requiring both:
2.1. Irregular menstrual cycles, defined as:
2.1.1. 1-3 years post menarche: <21 days or >45 days
2.1.2. >3 years post menarche: <21 or >35 days or <8 cycles per year
2.1.3. 1 year post menarche: >90 days for any cycle, or
2.1.4. Primary amenorrhoea by age 15 years or >3 years after thelarche
with
2.2. Biochemical or clinical hyperandrogenism such as significant hirsutism or severe acne

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
12 years

Upper age limit
19 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Current medical treatment for PCOS
2. Hormonal use within previous 3 months
3. Myoinositol use within previous 3 months
4. Other medical causes of hyperandrogenism such as idiopathic hyperandrogenism, non-classical congenital adrenal hyperplasia, thyroid dysfunction, hyperprolactinaemia, Cushing's syndrome and androgen-secreting tumour
5. Inability to provide consent, or inability to swallow tablets
6. Known allergy to any of the tablet ingredients
7. Unable to consent for participants aged 16 years and over
8. Cannot read or write English

Date of first enrolment
01/07/2026

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Childrens Hospital
Steelhouse Lane
Birmingham
England
B4 6NH

Study participating centre
Birmingham Womens Hospital
Mindelsohn Way
Birmingham
England
B15 2TG

Study participating centre
Liverpool Women's Hospital
Liverpool Womens Hospital
Crown Street
Liverpool
England
L8 7SS

Study participating centre
Alder Hay Childrens Hospital
Prescot Rd
Liverpool
England
L14 5AB

Study participating centre
St Michaels Hospital
Southwell Street
Bristol
England
BS2 8EG

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane
Colney
Norwich
England
NR4 7UY

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Funder Name
Action Medical Research

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available