

A multi-centre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia

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Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/11/2022	Condition category Urological and Genital Diseases	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 93/18/12

Study information

Scientific Title

A multi-centre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia

Study objectives

Each of the medical and surgical therapies available for the treatment of menorrhagia has different outcomes, risks and benefits. Women are likely to have different attitudes towards the trade-offs that present themselves when choosing a treatment. It is important, therefore, that women's preferences are taken into account when treatment decisions are being made. However, in order to share in decision making, women need structured and full information on menorrhagia and its treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Urological and genital diseases: Menstrual disorders

Interventions

Randomised controlled trial. This study is made up of two phases. Phase I will involve developing structured information on menorrhagia in the form of a booklet and a video, together with an interview protocol to be used to assess women's preferences regarding the treatment of the condition. In Phase II, 600 women with menorrhagia referred to one of five hospitals will be randomised to standard management or to a new management strategy involving the provision of structured information and the assessment of preferences using the package developed in

Phase I. Women will be followed-up over 2 years to assess the effectiveness and cost-effectiveness of the new management strategy. The extensive data collected in Phase II of the study will facilitate secondary analyses that will provide information to improve the effectiveness and cost-effectiveness of the management of menorrhagia.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Women will be followed-up over 2 years to assess the effectiveness and cost-effectiveness of the new management strategy. The primary outcome was health status, measured using the 36-item short-form general health survey (SF-36) instrument.

Secondary outcome measures

Secondary outcomes included women's treatment preferences, treatments undergone and satisfaction. In the economic analyses, health outcomes were measured in terms of quality-adjusted life-years (QALYs) based on women's responses to the EQ-5D (EuroQol-5 dimensions) instrument.

Overall study start date

01/10/1995

Completion date

31/08/2000

Eligibility**Key inclusion criteria**

Women with menorrhagia

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

200

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/10/1995

Date of final enrolment

31/08/2000

Locations

Countries of recruitment

Switzerland

United Kingdom

Study participating centre

Council on Health Research for Development

Geneva

Switzerland

CH-1201

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

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Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

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	HTA monograph	01/12/2003		Yes	No