# 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

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
25/04/2003		☐ Protocol		
Registration date 25/04/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 08/11/2022	Condition category Urological and Genital Diseases	Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

Protocol serial number 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

#### Study type(s)

Not Specified

#### 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 costeffectiveness 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(s)

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.

## Key secondary outcome(s))

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.

#### Completion date

31/08/2000

## Eligibility

#### Key inclusion criteria

Women with menorrhagia

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

#### 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

United Kingdom

Switzerland

## Study participating centre

## Council on Health Research for Development

Geneva Switzerland CH-1201

# Sponsor information

## Organisation

Department of Health (UK)

#### ROR

https://ror.org/03sbpja79

# Funder(s)

#### Funder type

Government

#### Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

## **Results and Publications**

## 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