

Open Access Tubal aSessment for the initial management of infertility in Primary Care

Submission date 30/09/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/05/2009	Condition category Pregnancy and Childbirth	<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
N0607138852

Study information

Scientific Title

Acronym

OATS

Study objectives

1. Does open access HSG allow quicker access to diagnosis, prognosis management plan for the fertile couple?
2. Qualitative interviews: Patient and professional: what are the views and perceptions of both traditional and open access HSG infertility management?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside NHS Local Research Ethics Committee approved on the 3rd March 2004 (ref: 2003/201)

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Fertility

Interventions

Cluster randomised controlled trial (RCT) in Newcastle, North Tyneside & Northumberland: control practices continue to manage infertility as they are currently and intervention practices have open access HSG available.

Qualitative Interviews will describe and compare experiences of patient and professional perceptions using a grounded approach to examine the attitudes and beliefs of couples through semi-structured one to one interviews.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Added May 2008: The primary outcome was the time between presentation to the GP and the couple receiving a diagnosis and management plan.

Secondary outcome measures

Added May 2008: Secondary outcomes were the uptake of open access HSG, frequency of diagnoses, first-line treatments offered, pregnancy rates and a measure of the extent of the information recorded and/or passed on in the referral letters of those subsequently referred.

Overall study start date

01/10/2004

Completion date

30/06/2007

Eligibility

Key inclusion criteria

RCT: Approximately 106 GPs in each arm assuming 75% recruitment (info from pilot data). To measure a 30% reduction (clinically significant) in time to appropriate treatment (per Royal College of Obstetricians and Gynaecologists (RCOG) guidelines) with a 90% power and 5% significance level assuming equal numbers in each arm of the study. This is achievable with a drop out rate of 40%.

Qualitative interviews: Random simple initially then purposive sampling to prove or refute the emergent theory/themes. Interviewees will be recruited from both arms of the RCT as well as professionals involved with infertility services.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Target recruitment: 212. Actual recruitment: 670 as of May 2008.

Key exclusion criteria

None, a pragmatic CRCT evaluating the effect of making open access HSG available to GPs for all infertile couples that present to them.

Date of first enrolment

01/10/2004

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Primary and Community care

Sunderland

United Kingdom

SR2 7BW

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

North Tyneside Primary Care Trust (UK)

Funder Name

Added May 2008: Award Sponsor the NHS National Coordinating Centre for Research Capacity Development (NCCRCD) (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	01/05/2009		Yes	No