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

Submission date	Recruitment status	[X] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/05/2009	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre

Department of Primary and Community care
Sunderland
United Kingdom
SR2 7BW

Sponsor information

Organisation
Department of Health

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

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