ISRCTN34841617 https://doi.org/10.1186/ISRCTN34841617

Trial of management of borderline and other low-grade abnormal smears

Submission date	Recruitment status	[_] Prospectively registered
25/10/2000	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2015	Urological and Genital Diseases	

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
G9700808

Study information

Scientific Title
Trial of management of borderline and other low-grade abnormal smears

Acronym

TOMBOLA

Study objectives
The purpose of this randomised trial is:
1. To determine whether a policy of cytological surveillance or initial colposcopy is the more effective and efficient policy for further investigation and clinical management in women with borderline abnormality or mild dyskaryosis.
2. To determine whether, following colposcopic examination of women with mild or borderline dyskaryosis, immediate LLETZ or biopsy and recall if appropriate for LLETZ, is the more effective and efficient method of treatment.
3. To evaluate the contribution of human papilloma virus (HPV) testing to the effectiveness and efficiency of the existing procedures for management of women with mild or borderline dyskaryosis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstetrics and gynaecology

Interventions
Interventions updated as of 14/02/2007:
1. Cytological surveillance versus initial colposcopy (R1)
2. Immediate large loop excision of the transformation zone (LLETZ) versus biopsy and selective recall for LLETZ (R2)

Interventions provided at time of registration:
Cytological surveillance/initial colposcopy

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Primary outcomes relating to effectiveness:
1. Cumulative incidence of CIN2 and CIN3 or more severe disease (referred to as CIN2/3), as determined by biopsy, up to and including the exit examination conducted three years after

enrolment
2. Point prevalence of CIN2/3, as determined by biopsy at the exit examination conducted three years after enrolment
3. For medium-term psychosocial effects of cytological surveillance versus initial colposcopy, cumulative proportion of clinically significant anxiety and/or depression, as determined by the Hospital Anxiety and Depression Scale (HADS), during the 34 month period after enrolment in the trial
4. For short-term psychosocial effects of immediate LLETZ versus biopsy and selective recall for LLETZ, (a) mean impact of events score, as determined by the Impact of Events Scale (IES) and (b) proportion of clinically significant anxiety and/or depression as determined by the HADS, at nine weeks after the initial colposcopy

Outcomes relating to efficiency:
1. Health related quality of life
2. Total Health Service resource use
3. Non-NHS costs

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/05/2008

Eligibility

Key inclusion criteria
1. An index smear which indicates mild dyskaryosis, or an index smear which indicates borderline dyskaryosis and a repeat smear taken 6 months later which shows borderline or mild dyskaryosis
2. Resident in Grampian Health Board Area, Tayside Health Board Area or in the Nottingham area with their smear processed by the Nottingham Cervical Screening Laboratory
3. Aged 20-59 years
4. Prior to the index smear, not have had an abnormal smear within the past 3 years
5. Not have had previous treatment for suspected cervical lesions
6. Not be pregnant
7. Not intend to move from the trial areas in the 3-year period following enrolment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria

Exclusions from R2: If colposcopy is unsatisfactory because the squamo-columnar junction is not visible, the woman will not be randomised but will be treated according to local clinical practice

Date of first enrolment
14/06/1999

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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 on cost effectiveness	28/07/2009		Yes	No
Results article	results on cytological surveillance versus initial colonoscopy	28/07/2009		Yes	No
Results article	results on large loop excision versus biopsy and selective recall	28/07/2009		Yes	No
Results article	results on comparison of EQ-5D and HADS	01/10/2009		Yes	No
Results article	management of low-grade results	01/05/2010		Yes	No
Results article	psychosocial impact results	18/01/2011		Yes	No
Results article	default from follow-up results	01/06/2012		Yes	No
Results article	results	01/12/2012		Yes	No
Results article	results	30/12/2013		Yes	No
Results article	results	01/01/2016		Yes	No
Protocol article	protocol	01/10/2006		Yes	No
Other publications	reasons for participation	01/10/2006		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes