

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

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2000	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 18/09/2015	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

Study website

<http://www.tombola.ac.uk/index.shtml>

Contact information

Type(s)

Scientific

Contact name

Dr Julian Little

Contact details

Department of Medicine & Therapeutics
University of Aberdeen
Foresterhill House Annex
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

14/06/1999

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

Age group

Adult

Sex

Female

Target number of participants

Modified 13/08/2009: Originally 10,000. Revised following changes to the eligibility criteria to 4483 (agreed by TSC in May 2000, ratified by MRC in January 2001)

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**

Scotland

United Kingdom

Study participating centre

University of Aberdeen

Aberdeen

United Kingdom

AB25 2ZD

Sponsor information**Organisation**

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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?
Other publications	reasons for participation	01/10/2006		Yes	No
Protocol article	protocol	01/10/2006		Yes	No
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