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Surgery versus Active Monitoring for LOw RISk Ductal Carcinoma in Situ (DCIS)

Submission date 22/05/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/05/2014	**Overall study status** Ongoing	
Last Edited 16/10/2023	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/a-trial-comparing-surgery-with-active-monitoring-for-low-risk-dcis-loris

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
16736

Study information

Scientific Title
A Phase III Trial of Surgery versus Active Monitoring for LOw RISk Ductal Carcinoma in Situ (DCIS)

Acronym
LORIS

Study objectives
The LORIS Trial aims to establish whether patients with newly diagnosed low risk DCIS can safely avoid surgery without detriment to their wellbeing (psychological and physical) and whether those patients who do require surgery can be identified by pathological and radiological means.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/WM/0083; First MREC approval date 28/04/2014

Study design
Phase III multicentre two-arm study with a built-in 2-year feasibility phase

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Ductal carcinoma in situ

Interventions
Comprehensive site training will be complimented by a patient-friendly DVD designed to ensure consistent and appropriate use of terminology. Patients will be randomised between standard surgery and active monitoring with annual mammography. Follow-up will be for a minimum of 10 years. Active Monitoring, Patients will be actively monitored by annual mammography.; Follow Up Length: 120 month(s); Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Ipsilateral invasive breast cancer free survival rate; Timepoint(s): 5 years

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/06/2014

Completion date
31/03/2030

Eligibility

Key inclusion criteria
1. Female, aged 46 years or above
2. Screendetected or incidental microcalcification (unilateral or bilateral)
3. Histologically confirmed diagnosis of nonhigh grade DCIS confirmed by local pathologist on either small volume
core biopsy or VACB (in accordance with the current NHSBSP Guidelines for Pathology Reporting in Breast Cancer
Screening)
4. DCIS diagnosed =90 days before registration
5. Able to give informed consent and comply with the trial schedule and completion of Patient Reported Outcome
questionnaires
6. Patient fit to undergo surgery
7. Written informed consent obtained

Participant type(s)
Patient

Age group
Adult

Lower age limit
46 Years

Sex
Female

Target number of participants
Planned Sample Size: 932; UK Sample Size: 932

Total final enrolment
181

Key exclusion criteria
1. Previous diagnosis of invasive cancer or ipsilateral DCIS (previous surgically treated contralateral DCIS is permitted)
2. A mass lesion clinically on mammogram or on ultrasound scan (if performed) at the site of the microcalcification
before biopsy
3. Any serious and/or unstable preexisting medical, psychiatric, or other condition that would prevent compliance with
the trial or consent process
4. Recent onset ipsilateral bloodstained nipple discharge, unless cytology and/or Ultrasound Scan (USS) confirmed
concomitant duct ectasia
5. High risk group for developing breast cancer (as defined in current NICE guidelines for familial breast cancer, or due
to prior exposure to mantle field radiotherapy)

Date of first enrolment
06/06/2014

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute for Cancer Studies
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details

Institute for Cancer studies
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England
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B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme; Grant Codes: 11/36/16

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

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?
HRA research summary			28/06/2023	No	No
Other publications		14/10/2023	16/10/2023	Yes	No