ISRCTN27544579 https://doi.org/10.1186/ISRCTN27544579

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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
46 years

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
University of Birmingham (UK)

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, Health Technology Assessment (HTA), HTA

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes