







Surgery versus Active Monitoring for LOW RISK Ductal Carcinoma in Situ (DCIS)

Submission date 22/05/2014	Recruitment status No longer recruiting	 Prospectively registered
		 Protocol not yet added
Registration date 22/05/2014	Overall study status Ongoing	 SAP not yet added
		 Results not yet expected
Last Edited 16/10/2023	Condition category Cancer	 Raw data not yet expected
		 Record updated in last year

Plain English Summary

<http://www.cancerresearchuk.org/about-cancer/trials/a-trial-comparing-surgery-with-active-monitoring-for-low-risk-dcis-loris>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

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 hypothesis

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

Condition

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

Overall study end date

31/03/2030

Eligibility**Participant inclusion criteria**

1. Female, aged 46 years or above
2. Screen-detected or incidental microcalcification (unilateral or bilateral)
3. Histologically confirmed diagnosis of non-high 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 \geq 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

Participant 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)

Recruitment start date

06/06/2014

Recruitment end date

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
Edgbaston
Birmingham
England
United Kingdom
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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