ISRCTN17160843 https://doi.org/10.1186/ISRCTN17160843

ROCkeTS: Refining Ovarian Cancer Test Accuracy Scores

Submission date 03/06/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/06/2015	**Overall study status** Completed	
Last Edited 04/10/2024	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-current-tests-for-ovarian-cancer-to-help-improve-diagnosis-rockets

Study website
https://www.birmingham.ac.uk/research/bctu/trials/pd/rockets/index.aspx

Contact information

Type(s)
Public

Contact name
Mr Ryan Ottridge

Contact details
University of Birmingham
Birmingham Clinical Trials Unit
Public Health Building
Birmingham
United Kingdom
B15 2TT
+44 121 415 9127
r.ottridge@bham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
168143

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 17994, IRAS 168143, RG_14-196

Study information

Scientific Title
Refining Ovarian Cancer Test Accuracy Scores: A test accuracy study to validate new risk scores in women with symptoms of suspected ovarian cancer.

Acronym
ROCkeTS

Study objectives
The ROCkeTS project aims to derive and validate new tests/risk prediction models that estimate the probability of having OC in women with symptoms. This project will be conducted in four interlinked phases

1. Phase 1 will be to undertake systematic reviews of the accuracy of tests and risk prediction models used for identifying OC in women with suspected OC.
2. Simultaneously, in phase 2 we will undertake refinement of an existing risk prediction model based on additional predictions within existing large datasets. For phase 2, we have identified 3 datasets, UKCTOCS, UKOPS and International Ovarian Tumour Analysis (IOTA) that are relevant to primary care and secondary care settings in post and premenopausal women.
3. Phase 3 prospective study: Based on the evidence from phases 1 and 2 , the most promising tests and risk prediction models for post and menopausal women will be externally validated, in a prospective study comprising newly presenting premenopausal and postmenopausal patients. In order to conduct this complex project as effectively as possible, we will start recruitment to the phase 3 study and banking of samples from patients concomitant with phases 1 and 2.
4. In Phase 4, we will develop models of pathways and cost comparisons of alternative testing. Pathways will incorporate the differences in patient management guided by different thresholds of the risk prediction models, that inform the minimum predicted probability that flags a diagnosis of OC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/12/2014, NRES Committee West Midlands - Solihull (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8269; solihull.rec@hra.nhs.uk), ref: 14 /WM/1241

Study design
Non-randomised; Interventional; Design type: Diagnosis

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Gynaecological Cancer; Disease: Ovary/Fallopian tube

Interventions
The new algorithm: The new test will be developed as part of phase 1 and 2 using biomarkers and ultrasound.
Follow Up Length: 12 month(s)

Intervention Type
Other

Primary outcome measure
Sensitivity of the new algorithm

Secondary outcome measures
Specificity of the new algorithm

Overall study start date
05/06/2015

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Pre and postmenopausal women with symptoms of suspected OC
and either:
2. Raised Ca125
3. Abnormal USG

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 2450; UK Sample Size: 2450; Description: 1050 premenopausal women and 1400 postmenopausal women

Key exclusion criteria
1. USG reveals non ovarian pathology, e.g. fibroids or simple ovarian cysts < 5cm in size (very low risk of malignancy)
2. Patients with normal pelvis USG
3. Patients who decline transvaginal scan
4. Patients unable to provide informed consent

Date of first enrolment
05/06/2015

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham Clinical Trials Unit
Division of Medical Sciences
Robert Aitken Institute
Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
Research Support Services – Research Governance
Birmingham

England
United Kingdom
B15 2TT
-
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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
31/10/2024

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/08/2016		Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/10/2024	04/10/2024	Yes	No