

ROCKeTS: Refining Ovarian Cancer Test Accuracy Scores

Submission date 03/06/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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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
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United Kingdom
B15 2TT

Sponsor information**Organisation**

University of Birmingham

Sponsor details

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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