ISRCTN16290169 https://doi.org/10.1186/ISRCTN16290169

Rational treatment selection for Merkel Cell Carcinoma (MCC)

Submission date 09/03/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/03/2016	**Overall study status** Completed	
Last Edited 10/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-improving-usual-treatment-newly-diagnosed-merkel-cell-cancer-rational-compare-trial-rational-review-study

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

20444

Study information

Scientific Title
Rational treatment selection for Merkel Cell Carcinoma (MCC): A randomised phase III multi-centre trial comparing radical surgery and radical radiotherapy as first definitive treatment for primary MCC with an observational study for patients ineligible for the randomised trial.

Study objectives
The aim of this study is to determine if radical surgery or radical radiotherapy as first definitive treatment
for the primary merkel cell carcinoma (MCC) results in better control of loco-regional disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/WM/0454

Study design
Multi-centre phase III randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Merkel cell carcinoma

Interventions
Participants are randomised to one of two study arms.

Arm A - Prioritise surgery: WLE of the primary site with radiotherapy reserved for later adjuvant treatment in selected patients.
Arm B - Prioritise radiotherapy: Early use of radical radiotherapy to the primary site without prior radical surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Time from randomisation to loco-regional treatment failure is determined from data collected throughout the study and up to 2 years of follow-up.

Secondary outcome measures
1. Progression free survival
2. Proportion of patients alive and free of disease
3. Quality of Life is measured at baseline, 3, 6, 9, 12 and 24 months from randomisation;
4. Survival
5. Time to distant progression
6. Time to local failure
7. Time to regional nodal failure

Overall study start date
31/03/2016

Completion date
30/09/2020

Eligibility

Key inclusion criteria
General inclusion criteria for all patients:
1. Patients newly diagnosed with histologically-proven MCC (either primary and/or regional nodal disease)
2. Completion of clinical and radiological staging investigations, including CT imaging (or other modality) of regional nodal basin(s) and major viscera (and SLNB if clinically appropriate) to identify regional and distant metastases
3. No distant metastases beyond the regional nodal basin (i.e. not stage IV disease)
4. Being considered for radical treatment to achieve long term disease control
5. Able to give valid informed consent
6. Consent for collection of data and tissue samples and follow up.
7. Life expectancy six months or greater in relation to general fitness and co-morbidities

Additional inclusion criteria for rational compare:
1. Patients newly diagnosed with histologically-proven primary MCC
2. In the opinion of the SSMDT, the primary MCC can be encompassed both within a wide surgical margin and within a radiotherapy field, and the SSMDT is in equipoise regarding WLE or radiotherapy as first treatment
3. Consent for randomisation into Rational Compare

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Key exclusion criteria
Exclusion criteria for rational compare only:
1. The primary MCC has already been treated radically with WLE (surgical margins >10 mm) or RT
2. Intended use of regional or systemic chemotherapy (including molecularly targeted agents and immunotherapy)

Date of first enrolment
31/03/2016

Date of final enrolment
30/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Institute for Cancer Studies
Edgbaston
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Sponsor information

Organisation
University of Birmingham

Sponsor details
Cancer Research UK Clinical Trials Unit
Edgbaston
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England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
14/03/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4.0	11/01/2019	10/10/2022	No	No

HRA research summary	28/06/2023	No	No