

Rational treatment selection for Merkel Cell Carcinoma (MCC)

Submission date 09/03/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

University of Birmingham

Institute for Cancer Studies

Edgbaston

Birmingham

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B15 2TT

Sponsor information

Organisation

University of Birmingham

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	11/01/2019	10/10/2022	No	No