

# Rational treatment selection for Merkel Cell Carcinoma (MCC)

<b>Submission date</b> 09/03/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/03/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/10/2022	<b>Condition category</b> 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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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B15 2TT

**Sponsor information****Organisation**

University of Birmingham

**Sponsor details**

Cancer Research UK Clinical Trials Unit

Edgbaston

Birmingham

England

United Kingdom

B15 2TT

**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?
<a href="#">Protocol file</a>	version 4.0	11/01/2019	10/10/2022	No	No

