

# A trial to assess whether nivolumab improves survival in relapsed mesothelioma more than placebo

<b>Submission date</b> 27/02/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/03/2017	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/12/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-nivolumab-for-mesothelioma-confirm>

## Contact information

### Type(s)

Public

### Contact name

Mrs Kelly Cozens

### Contact details

Southampton Clinical Trials Unit  
MP131  
Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

### Type(s)

Scientific

### Contact name

Dr Kayleigh Hill

### Contact details

Southampton Clinical Trials Unit  
MP131

Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
2016-003111-35

**ClinicalTrials.gov (NCT)**  
NCT03063450

**Central Portfolio Management System (CPMS)**  
32290

## **Study information**

### **Scientific Title**

CheckpOiNt blockade For Inhibition of Relapsed Mesothelioma (CONFIRM): A Phase III Trial to Evaluate the Efficacy of Nivolumab in Relapsed Mesothelioma

### **Acronym**

CONFIRM

### **Study objectives**

The aim of this study is to compare overall survival of nivolumab with placebo in patients with relapsed mesothelioma.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

West Midlands - Edgbaston Research Ethics Committee, 06/12/2016, ref: 16/WM/0472

### **Study design**

Randomised; Interventional; Design type: Treatment, Drug, Immunotherapy

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Mesothelioma

### **Interventions**

Patients will be randomised 2:1 to nivolumab or placebo, with twice as many people getting nivolumab as placebo. Randomisation will be stratified by site and epithelioid vs. non-epithelioid.

Active treatment arm: Patients will be treated with nivolumab at a dose of 240mg, every two weeks, infused over 30 minutes until disease progression, to a maximum of 12 months.

Placebo control arm: Patients will receive a placebo consisting of sterile 0.9% sodium chloride, every two weeks, infused over 30 minutes until disease progression, to a maximum of 12 months.

All patients will be followed up for a minimum 6 months and maximum of 5 years.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Nivolumab

## **Primary outcome(s)**

Overall survival will be calculated as time from randomisation until date of death

## **Key secondary outcome(s)**

1. Progression free survival is calculated as time from randomisation to disease progression by RECIST 1.1 or modified RECIST using CT scans at baseline compared to further CT scans after cycles 3 and 6 (each cycle is 14 days)
2. Overall response rate is measured by RECIST 1.1 or modified RECIST using CT scans at baseline compared to further CT scans after cycles 3 and 6 (each cycle is 14 days)
3. Quality of life is measured using EQ-5D-5L at baseline, after cycles 3 and 6 (each cycle is 14 days) and 1, 6 and 12 months post progression/treatment discontinuation
4. Toxicity is measured using CTCAE V4.03 at baseline, after each treatment cycle (each cycle is 14 days) and each follow up visit
5. Cost effectiveness is measured using a health resource use questionnaire at baseline, after cycles 3 and 6 (each cycle is 14 days) and 1, 6 and 12 months post progression/treatment discontinuation

## **Completion date**

30/09/2022

# **Eligibility**

## **Key inclusion criteria**

1. Histological confirmation of mesothelioma
2. Prior treatment with at least two lines of platinum based chemotherapy
3. ECOG Performance Status 0-1
4. Evidence of disease progression (which is radiologically assessable through RECIST) on CT scan within 28 days of trial treatment
5. Age 18 and above
6. Screening laboratory values within protocol specified ranges
7. Willing to use adequate contraception methods where applicable

8. Willing to provide blood and tissue samples relating to mesothelioma
9. Expected survival of at least 12 weeks

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

332

**Key exclusion criteria**

1. Untreated, symptomatic CNS metastases
2. Carcinomatous meningitis
3. Active, known or suspected auto-immune disease
4. Those requiring systemic treatment with corticosteroids or immunosuppressive medications within 14 days of planned first dose
5. Other active malignancy requiring treatment
6. Serious or uncontrolled medical disorder or active infection which would impact on the trial or affect their involvement
7. Prior treatment with anti-PD-L1, anti-PD-L2, anti-CD137 or anti-CTLA-4 antibody
8. History of testing positive for HIV or AIDS or a positive test for Hepatitis indicating acute or chronic infection
9. History of allergy or sensitivity to monoclonal antibodies
10. Women who are pregnant or breastfeeding

**Date of first enrolment**

27/03/2017

**Date of final enrolment**

27/03/2020

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Southampton Clinical Trials Unit**  
MP131  
Southampton General Hospital  
Tremona Road  
Southampton  
England  
SO16 6YD

## Sponsor information

**Organisation**  
University of Southampton

**ROR**  
<https://ror.org/01ryk1543>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancer Research UK

**Alternative Name(s)**  
CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available for sharing via controlled access by authorised Southampton CTU (SCTU) staff (as delegated to SCTU by the trial sponsor) and anonymised IPD within the clinical trial dataset will be available for sharing via open access after the trial is published.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		14/10/2021	22/10/2024	Yes	No
<a href="#">Protocol article</a>		18/04/2018	05/10/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			18/12/2025	No	Yes
<a href="#">Statistical Analysis Plan</a>	version 3	01/08/2022	11/10/2023	No	No