ISRCTN79814141 https://doi.org/10.1186/ISRCTN79814141

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

Submission date 27/02/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/03/2017	**Overall study status** Completed	
Last Edited 29/11/2024	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-nivolumab-for-mesothelioma-confirm#undefined

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Public

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Additional identifiers

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

ClinicalTrials.gov (NCT)
NCT03063450

Protocol serial number
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
Adult

Lower age limit
18 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
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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?
Results article		14/10/2021	22/10/2024	Yes	No
Protocol article		18/04/2018	05/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 3	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		01/08/2022	11/10/2023	No	No