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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

EudraCT/CTIS number
2016-003111-35

IRAS number

ClinicalTrials.gov number
NCT03063450

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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

Overall study start date
01/10/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 336; UK Sample Size: 336

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
England

United Kingdom

Study participating centre
Southampton Clinical Trials Unit
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the trial will be published in a high-impact peer reviewed scientific journal around six months after overall trial end date.

Intention to publish date
30/09/2023

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