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EURO EWING Consortium EEC

@CRCTU Cancer Research UK Clinical Trials Unit

9th rEECur Newsletter

Issue 9

rEECur@trials.bham.ac.uk

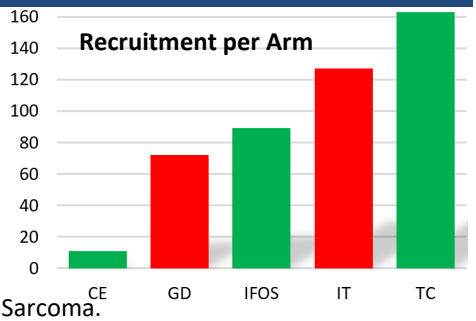
2nd December 2021

TRIAL UPDATE

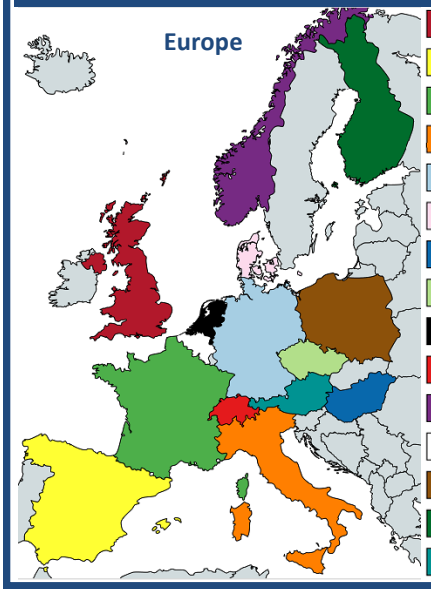
Welcome to the 9th rEECur newsletter. Since our last newsletter we have 3 major milestones to announce:

1. The Topotecan and Cyclophosphamide (TC) arm permanently closed to recruitment in October 2021.
2. We now have over 460 patients recruited to the study.
3. The data monitoring committee congratulated all sites on data completeness ahead of the interim analysis - the highest data return level to date at >97%!

We would like to thank you for your support of rEECur - the first study to build a robust, randomised evidence base of treatment efficacy/toxicity in relapse Ewing Sarcoma.



Recruitment by Country



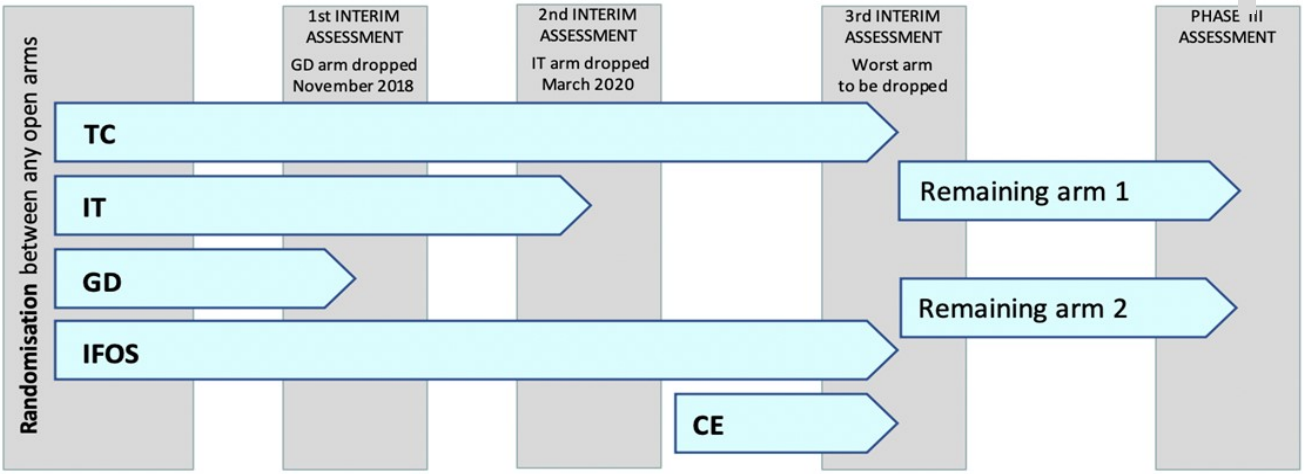
- United Kingdom - 131
- Spain - 109
- France - 77
- Italy - 65
- Germany - 20
- Denmark - 10
- Hungary - 8
- Czech Republic - 7
- Netherlands - 6
- Switzerland - 4
- Norway - 5
- Belgium - 4
- Poland - 1
- Finland - 1
- Austria - 0

Top 5 Recruiting Sites	No. of PTS
Hospital Virgen Del Rocio, Spain	28
Istituto Ortopedico Rizzoli, Italy	26
University College London Hospital, UK	22
Hospital Politecnico U La Fe, Spain	14
Centre Leon Berard, France	13

Permanent Closure of the Topotecan and Cyclophosphamide (TC) Arm

The TC arm permanently closed to recruitment on 21-Oct-2021. The data monitoring committee made this recommendation on the basis of differences between the TC and high dose ifosfamide (IFOS) arms in overall survival (OS) and event-free survival (EFS). There were no safety concerns. However, TC is not an inactive regimen. TC has performed better than the Gemcitabine & Docetaxel (GD) and Irinotecan & Temozolomide (IT) combinations on the basis of imaging response, EFS and OS, and all of the regimens tested in rEECur are considered to be active regimens in this setting. Recruitment continues to the remaining arms IFOS and carboplatin & etoposide (CE). Follow-up continues for all patients as per protocol.

TRIAL DESIGN



Quality of Life (QoL) Sub-study

Please remember to provide QoL questionnaires at:

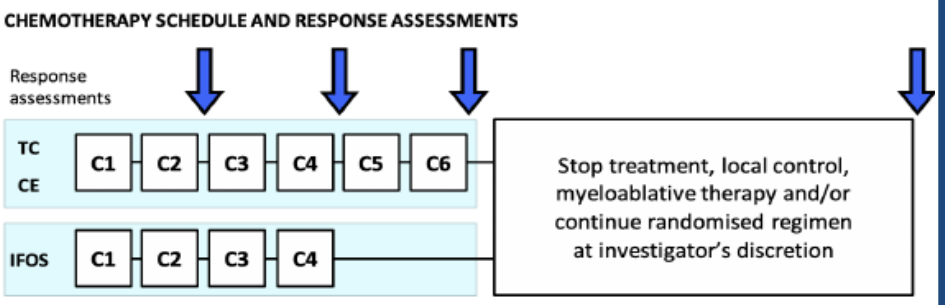
Baseline ➡ **After Cycle 2** ➡ **After Cycle 4**

If a QoL was not done, please let the trial office know and we will remove it from the monthly data

Protocol Compliance

We would like to remind sites of the importance of adhering to protocol dose schedules and imaging time-points. This is essential to maintain trial integrity, despite these being standard of care regimens.

Patients should receive the **correct dose of treatment as per protocol** according to their body surface area. Response scans must be done after Cycles 2, 4, (and 6 for CE only) and at the end of all treatment. Imaging must be reported according to RECIST 1.1 criteria.



Eligibility Assessments

The eligibility criteria have changed as per protocol v6.0 — see eligibility checklist v4.0

Key points include:

Any queries should be directed to the trial office and respective NCCs.

1. Age ≥2 years with no upper age limit
2. Date of planned randomisation within 4 weeks of baseline imaging
3. Radiological evidence of disease progression during or after completion of first or any subsequent line of treatment
   This means disease progression must be demonstrated after the latest treatment received, before entry onto rEECur. This includes if all disease areas have been resected prior enrolment onto rEECur. Radiotherapy to target lesion within previous six weeks is an exclusion criterion. If the target lesion is the sole area of disease, there must be further evidence of disease progression before trial entry.
4. Patients must not have any contraindication to any IMP in the two available arms (CE and IFOS)
   and
5. Patients must be medically fit to receive full protocol directed doses of trial treatment at trial entry
   These mean patients with pre-existing medical conditions are eligible to enter the trial if they meet all inclusion and no exclusion criteria and do not have any condition requiring a dose modification at cycle 1.

PET-CT Sub-Study

PETCT scans are due at Baseline and post Cycle 4. Thank you to all sites who have contributed PET-CT images to include in the PET-CT sub-study. Analysis will start as soon as all scans are collected.

Please remember that appropriate consent must be in place and all **scans must be fully anonymised** according to the instructions provided in the PETCT Manual before couriering.

Christmas Period Emergency Contact Details

The Cancer Research Clinical Trials Unit (CRCTU), Birmingham will be closed over the Christmas period from Thursday 23rd December - Monday 3rd January (inclusive).

Dr Martin McCabe will provide emergency cover during this period. In the case of an emergency, please call the Christie Hospital switchboard on **+44161 446 3000** and ask to be put through to Dr Martin McCabe's mobile phone.

Please continue to report SAEs within 24 hours of becoming aware of the event to **reg@trials.bham.ac.uk**

Contact the rEECur Trial Team

We wish you all a very Merry Christmas & Happy New Year!

We are operating a mixed model of home and office working during the COVID-19 pandemic.

Please do not contact our usual office/landline number and instead continue to email the rEECur trial mailbox.

Office hours 09:00-17:00 GMT, Monday-Friday ✉ **reecur@trials.bham.ac.uk**