COMBINAIR 3
Ewing très haut risque métastases extra-pulmonaires
2-50 ans
N. CORRADINI, pédiatre, IHOPE, Lyon; V. LAURENCE, oncologue médicale, Curie

Etude de phase II multicentrique non randomisée non comparative
Objectif primaire : effet antitumoral évalué par EFS à 18 mois

Études ancillaires : MDD/MRD sg et MO + profils transcriptomiques
Ouverture centres 4ème trimestre 2016
Phase 2 randomisée d'association du MEPACT à la chimiothérapie post-opératoire dans les ostéosarcomes de haut risque (métastatiques ou localisés avec une mauvaise réponse histologique)

PI: Nathalie GASPAR, Sophie Piperno-Newman
Statisticien : Marie-Cécile Le Deley
Sponsor : UNICANCER

PHRC 2016 : Acceptation de la lettre d’intension
Accrual over a 3-year period

Sarcome 13

Pre-op chemo

Surgery

MTX-strata

Met Or Loc PR

Risk group

R

+/– MEPACT 2mg/m2 IV twice weekly for 12 weeks, then weekly for 24 weeks (48 doses over 36 weeks)

MTX 12g/m2 x 1d

A : Adriamycine 37.5 mg/m² x 2d

P : Cisplatinum 100 mg/m² x 1d

I : Ifosfamide 3 g/m² x 2d

2 years Follow-up

Accrual over a 3-year period
Objectives

• Primary:
  To estimate the impact on the 3y-EFS of the addition of MEPACT during 36 weeks to first-line post-operative chemotherapy in patients < 40 years with high risk osteosarcoma (metastatic status and/or with poor histological response)

• Study design:
  Randomized phase II first-line trial
  Final analysis will be:
  • performed as soon as 34 events have been observed, or 105 pts accrued
  • based on all included patients (Intention-to-treat analysis)
Frontline and Relapse study for patients with RMS

The FaR-RMS Study

Gianni Bisogno       Julia Chisholm
Gian Luca de Salvo   Nicola Fenwick
Anna Kelsey          Meriel Jenney
Henry Mandeville     Helene Martelli
Kieran McHugh        Hans Merks
Veronique Minard-Colin Veronica Moroz
Joshua Savage        Janet Shipley
Keith Wheatley
Principles

“Overarching” study for all newly diagnosed and relapsed patients

- Children and Adults (exclusion pleiomorphic RMS)

- Build Structure to be able to bring in new agents and adapt protocol

- Ask randomised questions where evidence is not clear
- MAMS design
Frontline Randomisation

FaR-RMS
Trial Schema

Phase Ib
IrlIVA
IVA+new
Radiotherapy randomisation

FaR-RMS
Trial Schema

Localised disease

Y

RT1A

Pre-op RT

RT1B

Higher LFR

41.4 Gy

50.4 Gy

Post-op RT

Local failure risk

RT1C

Higher LFR

41.4 Gy

50.4 Gy

Incomplete response

Standard LFR

59.4 Gy

N

Complete response

Standard LFR

50.4 Gy

Is disease resectable?

Y

N

Localised disease

Limited Metastatic Disease

Radical RT to all disease sites

Stereotactic ablative RT (SABR/SRS) or Fractionated conformal RT

Extensive Metastatic Disease

RT2

RT to all sites of disease

RT to Primary tumour & regional lymph node mets
Relapses Randomisations

FaR-RMS
Trial Schema