Article details

Title of article
OCEAN: a randomized Phase III study of melflufen + dexamethasone to treat relapsed refractory multiple myeloma

Authors
Fredrik Schjesvold, Pawel Robak, Ludek Pour, Johan Aschan & Pieter Sonneveld

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Study registration number
NCT03151811

Objectives/rationale

Primary objective - Arm A (experimental):

Compare PFS of patients in the experimental arm (melflufen* + dexamethasone) with those in the control arm (pomalidomide + dexamethasone)

Secondary objectives - Arm B (control):

Compare the ORR, DOR, OS and safety between the experimental arm (melflufen* + dexamethasone) and the control arm (pomalidomide + dexamethasone)

Study design and treatment

Arm A (experimental):
40 mg melflufen* intravenously on Day 1 of each 28-day cycle and 40 mg dexamethasone orally on days 1, 8, 15 and 22 of each cycle

Arm B (control):
4 mg pomalidomide capsules orally on days 1–21 of each 28-day cycle and 40 mg dexamethasone orally on days 1, 8, 15 and 22 of each cycle

Planned sample size:
450 patients from ~140 sites

21 countries

Planned study period:
12 June 2017 to Q1 2022 (estimated completion)

Efficacy assessments:
M-protein assessment, skeletal X-rays and/or CT scan of bones, bone marrow aspirate, imaging procedures of known or suspected extramedullary plasmacytomas and calcium assessment

Safety assessments:
AEs, physical assessments (vital signs, neurological assessment and performance status assessment), routine safety laboratory tests, chest X-rays, hepatitis B screens, pregnancy testing and electrocardiograms

Key eligibility criteria

Adult patients with RRMM refractory to both lenalidomide and last line of treatment

Must have received 2–4 lines of treatment (including lenalidomide and a PI)

Must not have received pomalidomide prior to study, be primary refractory, have select co-morbid conditions or have residual side effects from prior therapy > grade 1

Outcome measures/endpoints

Primary endpoints

- PFS

Secondary endpoints

- ORR
- DOR
- OS
- Safety

Glossary

*International Non-proprietary Name (INN): melphalan flufenamide
AE: Adverse event; CT: Computed tomography; DOR: Duration of response; MM: Multiple myeloma; M-protein: Monoclonal protein; ORR: Overall response rate; OS: Overall survival; PFS: Progression-free survival; PI: Proteasome inhibitor; RRMM: Relapsed refractory multiple myeloma.