Purpose/Objective
The EXTREME regimen (6 cycles of 5FU-cisplatin-cetuximab followed by cetuximab maintenance) is currently the standard of care in first line recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC). The GORTEC phase II trial evaluating the TPEx regimen (4 cycles of docetaxel–cisplatin-cetuximab followed by cetuximab maintenance) demonstrated good results (median overall survival (OS) 14 months, overall response rate 54%) with acceptable safety profile, excellent dose intensity, high rate of patients who started maintenance and easy implementation. The aim of the current trial is to compare TPEx and EXTREME regimens.

Study design

Main Inclusion Criteria
- R/M HNSCC not suitable for locoregional treatment
- No prior systemic chemotherapy for HNSCC
- Age 18-70 years
- PS <2
- Creatinine clearance >60 ml/min
- Prior total dose of cisplatin ≤ 300 mg/m²

Primary Endpoint
Overall Survival

Secondary Endpoints
- Objective Response Rate
- Best Response Rate
- Progression Free Survival
- Time-to-progression
- Toxicity
- Quality of Life
- Cost-effectiveness study

Conclusion
This randomized trial will establish if TPEx regimen is a relevant substitute for EXTREME as 1st line treatment in fit patients with R/M HNSCC.

References
2. Guigay J, Fayette J, Dillies AF, et al, Ann Oncol 2015 (Accepted for publication)