

INTEGRATE IIa

Improving survival for people with gastro-oesophageal cancer

Regorafenib improved overall survival in patients with refractory advanced gastro-oesophageal carcinoma (AGOC) by around 30%.

EXPERTISE

Conceived, designed and conducted in collaboration with ANZUP. Expertly designed methodology and endpoints incorporating the potential for prognostic biomarker review for AGOC patients.

Trial snapshot

Start date: 2016

End date: 2022



251

participants
40 sites
5 countries

Collaborators:

- AGITG
- Bayer

BACKGROUND

Gastric cancer is currently the fifth most common cancer (5.6% of all new cases), and the fourth most common cause of cancer-related deaths worldwide (7.7% of all deaths). For advanced gastro-oesophageal carcinoma (AGOC) there remains a poor prognosis, with chemotherapy or biologic therapy in the refractory setting associated with a median overall survival of less than six months and real-world data in stage IV disease associated with a 2-year overall survival of less than 10%.

STUDY OVERVIEW

The Integrate IIa study followed the success of the Phase II INTEGRATE study, which demonstrated a positive signal with regorafenib.

The purpose of INTEGRATE IIa was to see if Regorafenib improved overall survival as a third line therapy in refractory AGOC. The primary objective is overall survival, while secondary objectives include progression free survival, objective response rates, safety, quality of life, and investigation in patient populations from different geographic regions.

KEY FINDINGS

The Integrate IIa trial has helped to answer an important health question for patients with refractory advanced gastro-oesophageal carcinoma (AGOC). It has provided evidence that a new treatment, regorafenib, acts against the tumour and is safe and effective.

Findings from Integrate II have shown that regorafenib can improve overall survival by about 30% in these patients.

Regorafenib is the first oral multi-targeted tyrosine kinase inhibitor (TKI) to demonstrate improved overall survival in a mixed population of Asian and non-Asian patients with metastatic or locally recurrent gastro-oesophageal cancer.