



EORTC
European Organization for Research
and Treatment of Cancer

Development of an EORTC quality of life module for G.I.-related Neuroendocrine Tumours: UPDATE

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AIMS

- To test the scale structure, reliability and validity of the gastrointestinal NET module (QLQ-G.I.NET21)
- To develop a questionnaire specific to G.I. neuroendocrine tumours which determines if treatments are having an effect on improving QOL

Phase 4

- 400 patients needed over the next 3 years
- 18 sites have shown interested,
- 11 active sites
- 4 sites no patients recruited yet
- 3 sites awaiting ethical approval
- Ipsen has shown interested and will fund additional sites in Germany

Recruitment

■ European

- Sweden- Gunnel Larsson-13 patients
- Spain- Dr Diaz- 8 patients
- Germany- Jessica Tademacher- 6patients
- Italy- Olimpia Pino- 5 patients
- Netherlands- Baabs Taal- 4 patients

UK sites

- Kings College- 5 patients
- Liverpool- 2 patients
- Royal Free- 1 patient
- Southampton- 1 patient
- Hampshire Clinic- 1 patient
- Basingstoke- 14 patients

Patient Groups

- 3 Treatment Groups
- Group 1 Somatostatin analogues or Interferon treatment
- Group 2 Radionuclide therapy or chemotherapy treatment
- Group 3 Ablative Therapies and Liver surgery

Phase 4

- Each patient will undergo 3 assessments, pre treatment and then month 3 and 6 post treatment
- 80 patients will be involved in test-retest two weeks after the 6 month assessment

Validity

- Correlation Analyses ie social function of C30 will correlate with social scale of G.I.NET
- Group Comparisons ie Karnofsky performance status at time of assessment and disease stage
- Responsiveness to Clinical Change ie improvement or deterioration in health status

Time Scale

- All patients asked at 6 month follow up
“Which would be the best time scale to use in this questionnaire – is it 1 week, 4 weeks or no preference?”

Summary

- Any new sites?
- Are there any problems or issues?