



Central South Coast
Cancer Research Network

Validation of a disease-specific questionnaire module in assessing the quality of life of patients with G.I.-related NET.

Phase 4 Study

NET / Carcinoid Tumours

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Study Statistician Dr Ghasem Yadegarfar

Brussels Meeting

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Phase 4 validation study

Aims of Study

- Development of NET specific module
- Test scale structure, reliability and validity of G.I.-NET module(G.I.NET21)
- Assess quality of life using C30 and G.I.NET21 before and after various treatments



Inclusion Criteria

- Histological diagnosis of NET or radiological findings with raised hormones in plasma or urine
- Eligible diagnoses with/out hormones
 1. Gut primary with liver mets
 2. Lung primary with liver/abdominal mets
 3. Pancreas primary with/out mets
- Patients to start a treatment for NET, and will be put into groups 1, 2 or 3 depending on the treatment they receive.



Treatment Groups

Group 1: Somatostatin Analogues or Interferon

- Patients be SMS or interferon naive
- Dose escalation is allowed
- Other treatments avoided, if possible.

Group 2: Radionuclide therapy or chemotherapy-2-6 treatments.

- Further group 2 treatments can be given
- Avoid group 3 treatments
- Assessments not done week of and week after treatment.



Treatment groups

Group 3: Embolisation (hepatic artery or chemotherapy) or surgery-single treatment.

- Avoid further group 2 or 3 treatments

For Groups 2 and 3

Not had group 2 or 3 treatment within past 6 months

Patients can be on a stable dose of group 1 treatment and dose not change by more than 50% during the study.



Assessment schedule

1 st assessment	2 nd assessment	3 rd assessment	Test re-test assessment
Within 3 weeks before treatment	3 months (+/- 3 weeks)	6 months (+/- 3 weeks)	2 weeks after assessment 3 for stable patients

No trial treatment 14 days before or during assessment
for group 2(chemotherapy, radio nucleotide therapy)



Study Documentation

Assessment 1:

- QLQ-C30 and G.I.NET21
- Debriefing questionnaire
- Karnofsky performance status
- Eligibility form
- Clinical data and socio-demographic form



Study documentation

Assessment 2 and 3:

- QLQ-C30 and G.I.NET21
- Karnofsky performance status
- Follow-up form

Test-retest assessment:

- For stable patients repeat assessment done 2 weeks after assessment 3



Investigators

Awaiting ethics approval

- Louise Jones-Liverpool, UK.
- Dr Joy Ardill, Northern Ireland
- Professor Larry Kvols -USA
- Dr Gregory Kaltsas-Greece (pilot testing completed)



Awaiting Pilot Testing

- Germany-completed but awaiting approval

Dr Sezer, Dr Fleissner

Dr Koller

- Denmark-need another 3 patients

Dr Henning Gronbaek, Lone Astrup

- Italy

Dr Falconi and Dr Bettini

Professor Olimpia Pino



Recruitment

10 patients in total

- Sweden=6
- Spain=1
- Basingstoke, UK=3



Translations

Translations Co-ordinator -Linda Dewolf

- Completed in
Swedish, German, Dutch, Italian, Greek, Hungarian,
French, Italian, Polish, Spanish, Czech,
Danish, Portuguese, Hebrew.
- Requested in
Norwegian