

**Presentazione di un trial clinico con impiego
di un analogo della somatostatina in
pazienti con
carcinoma polmonare a piccole cellule**
Overview e rationale

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SMALL-CELL LUNG CANCER (SCLC)

About 20% of all lung cancer,
~5,000 new cases/year in Italy;

High biological aggressiveness,
doubling time ~ 50 days

Early dissemination,
about 2/3 of patients present
with extended disease at
diagnosis



Many active drugs, but poor overall outcome:

5% survival rate at 5 yrs

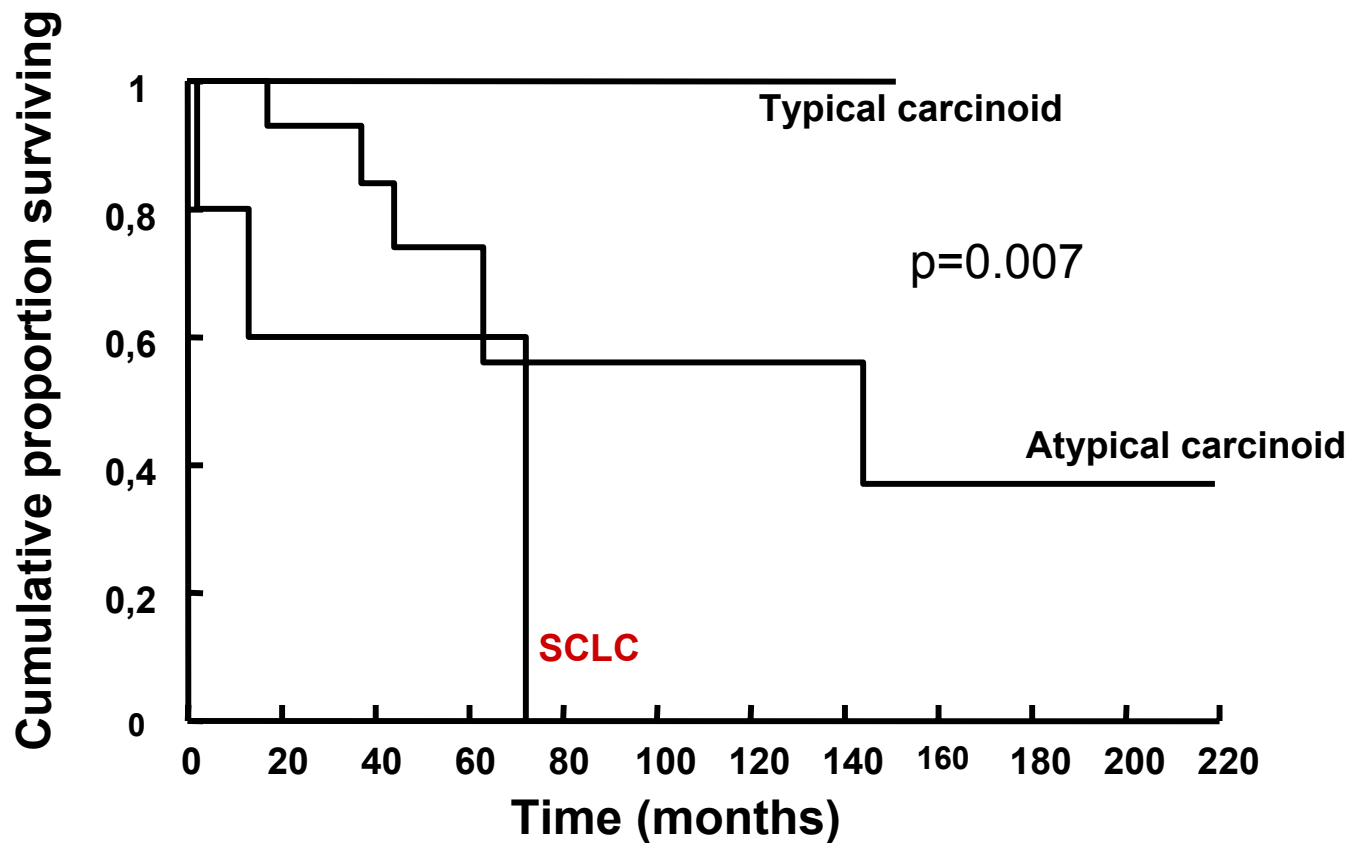
LUNG TUMORS - CASE STUDY

Clinica Chirurgica - Università "G. D'Annunzio, Chieti-Pescara

(1973-1998)

NSCLC	3789	EXERESES	1267
SCLC	348	EXERESES	68
CARCINOID	51	EXERESES	51
OTHER PRIMAY MALIGNANCIES	29	EXERESES	10
METASTASES	287	EXERESES	102
BORDERLINE AND BENIGN	157	EXERESES	112
TOTAL	4661		1610

Survival of patients with NE lung tumors

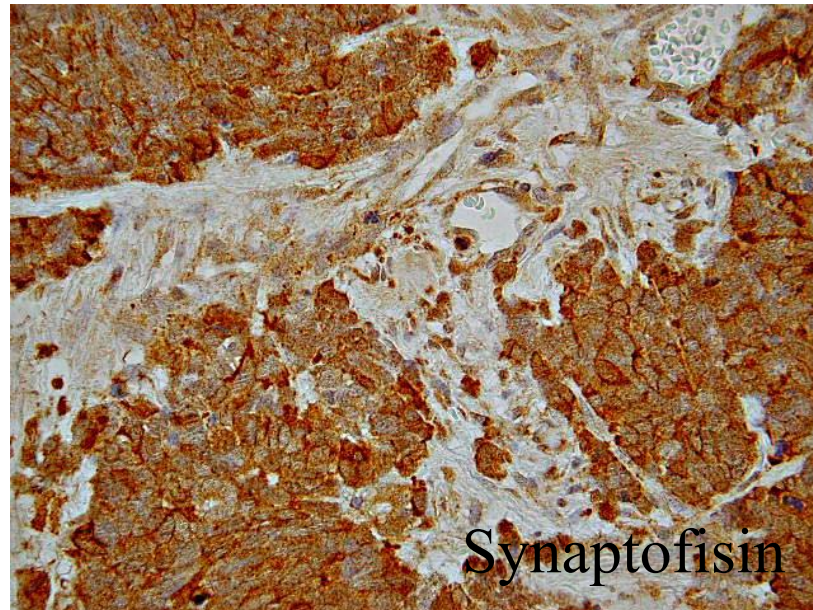
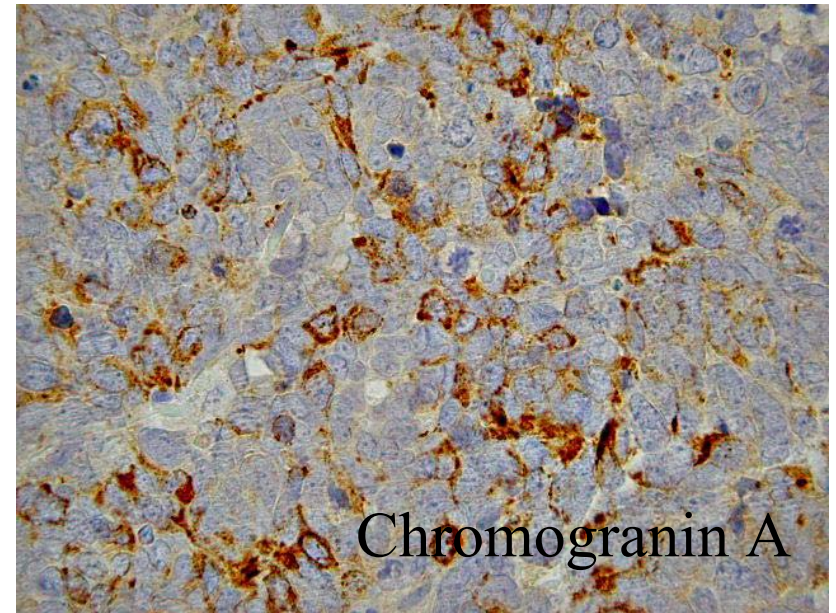
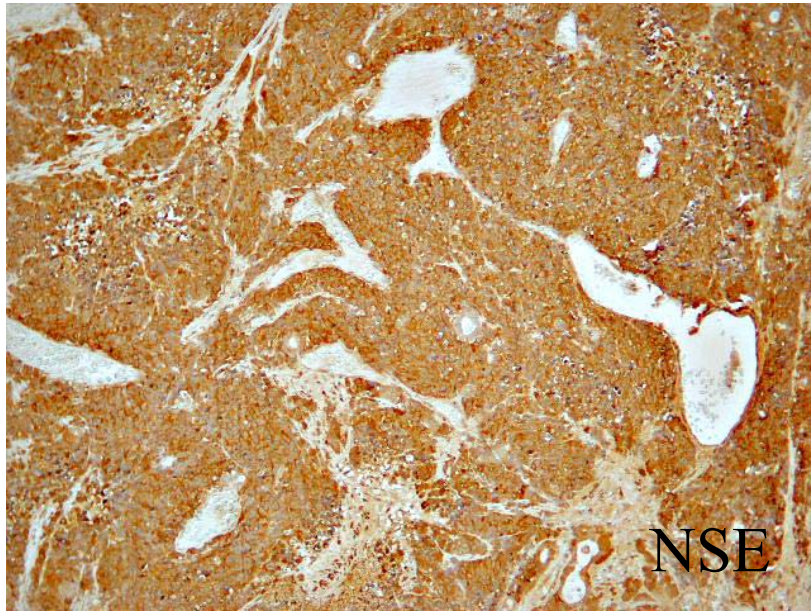


RATIONALE FOR THE USE OF SMS ANALOGUES IN SCLC

1. SCLC belongs to the Neuroendocrine Tumors;
2. Functional SMS receptors have been identified in SCLC cells;
3. SMS and its analogues display antiproliferative and anti-angiogenetic activities;
4. SMS analogues are potent suppressors of the growth of SCLC in nude mice

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NEUROENDOCRINE TUMORS OF THE LUNG

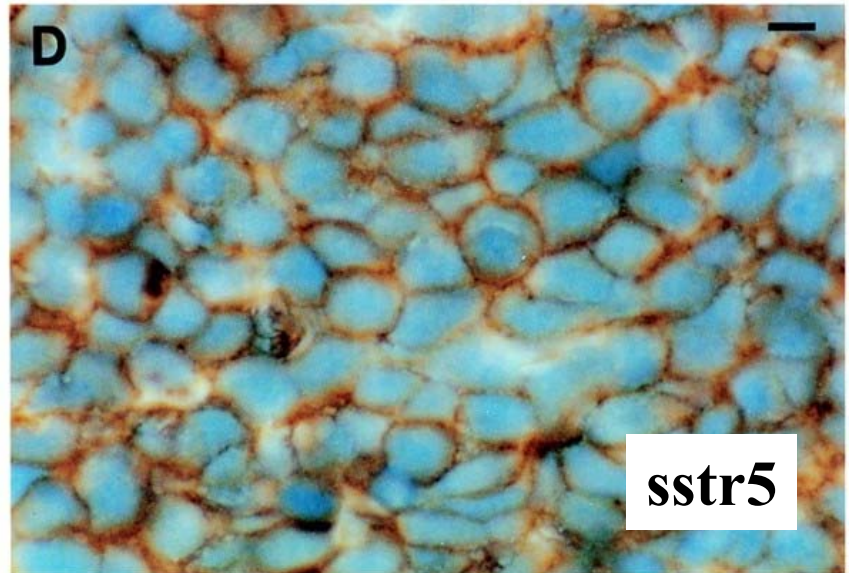
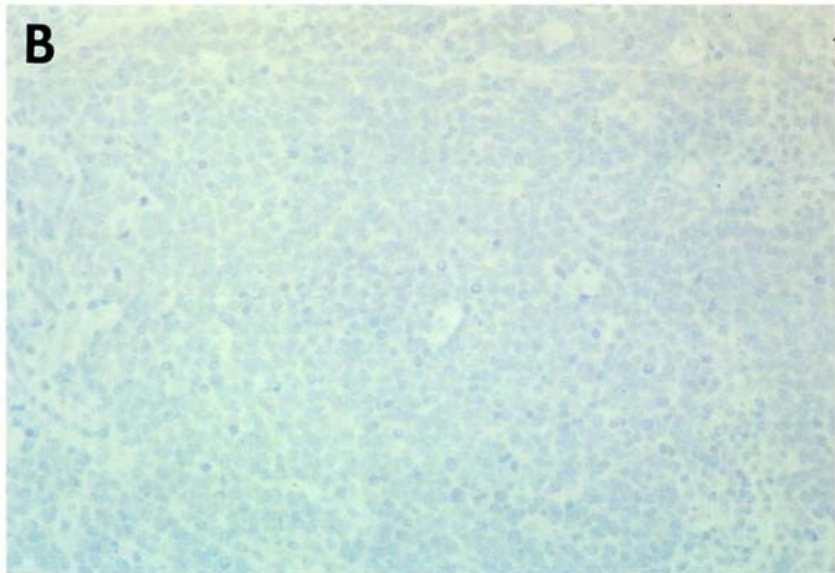
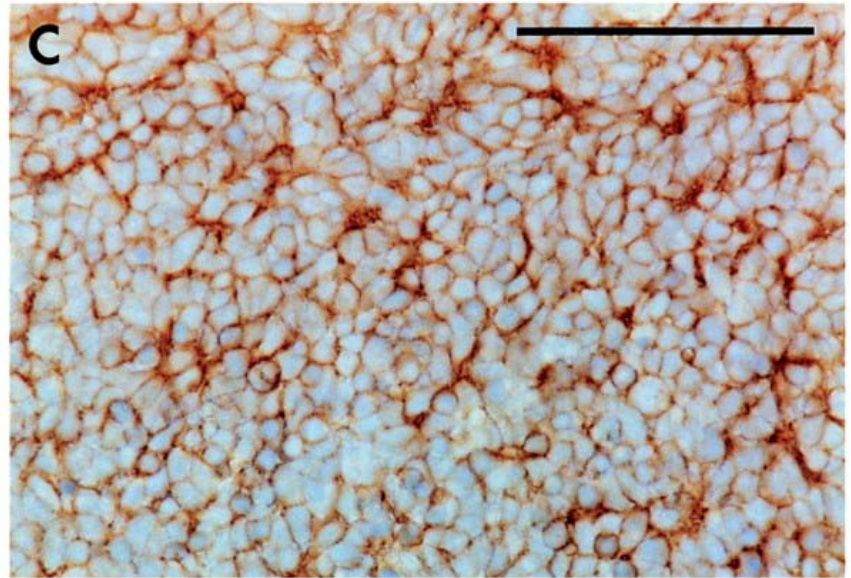
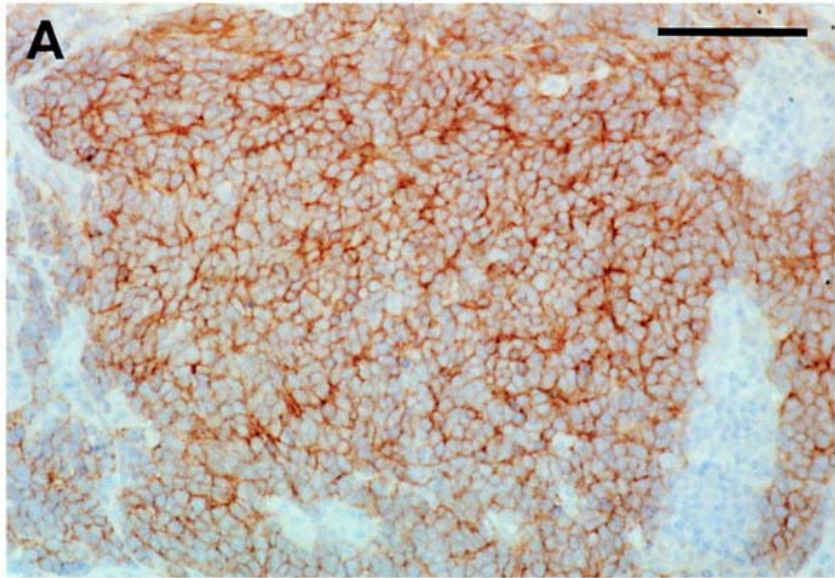
New Hystological Classification

(After WHO)

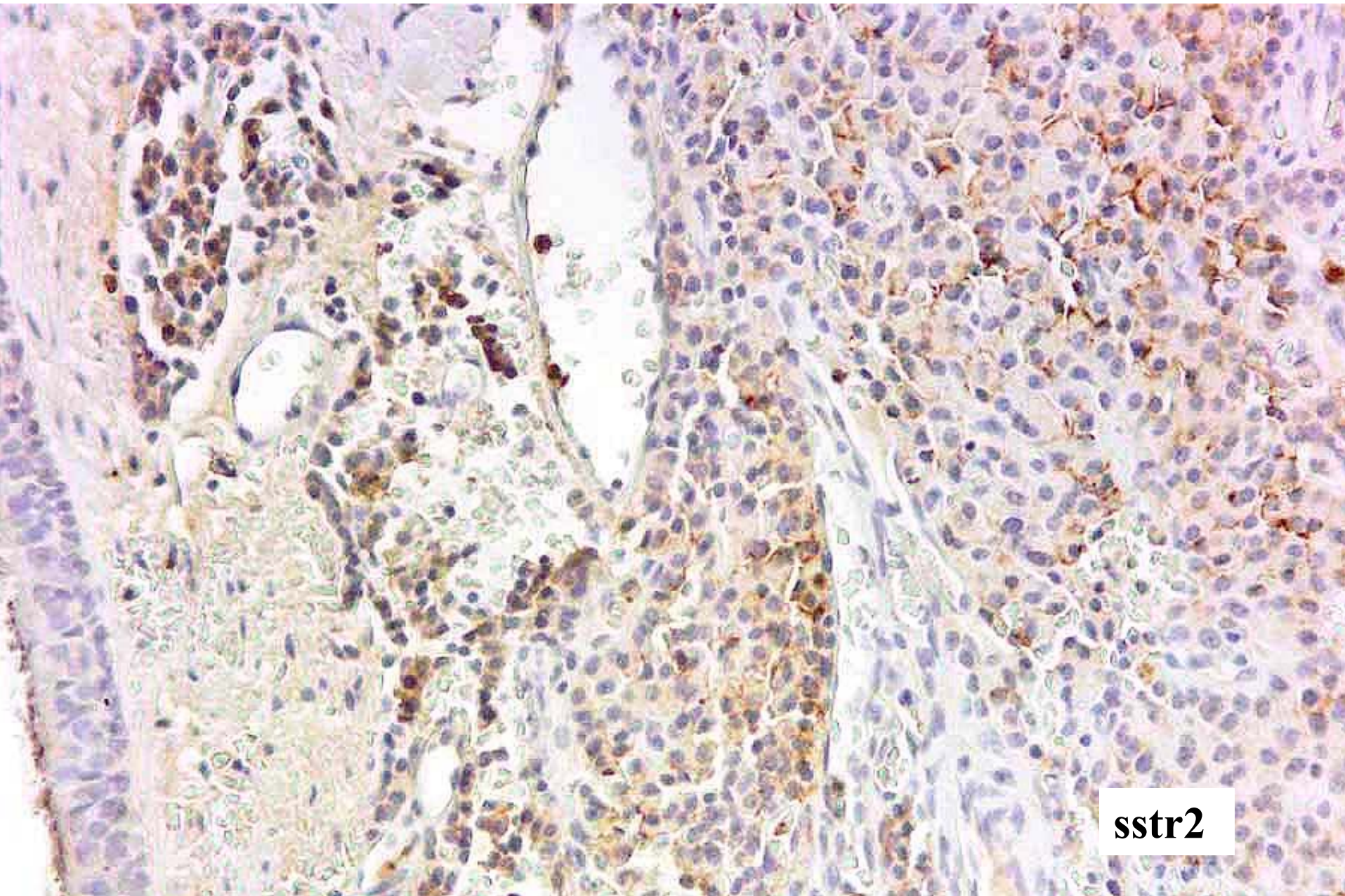
1. Well differentiated neuroendocrine carcinoma
(CARCINOID TUMOR)
2. Moderately differentiated neuroendocrine carcinoma
(ATYPICAL CARCINOID)
3. Poorly differentiated neuroendocrine carcinoma
 - **Small cell carcinoma (SCLC)**
 - Mixed small cell/large cell carcinoma
 - Large cell neuroendocrine carcinoma

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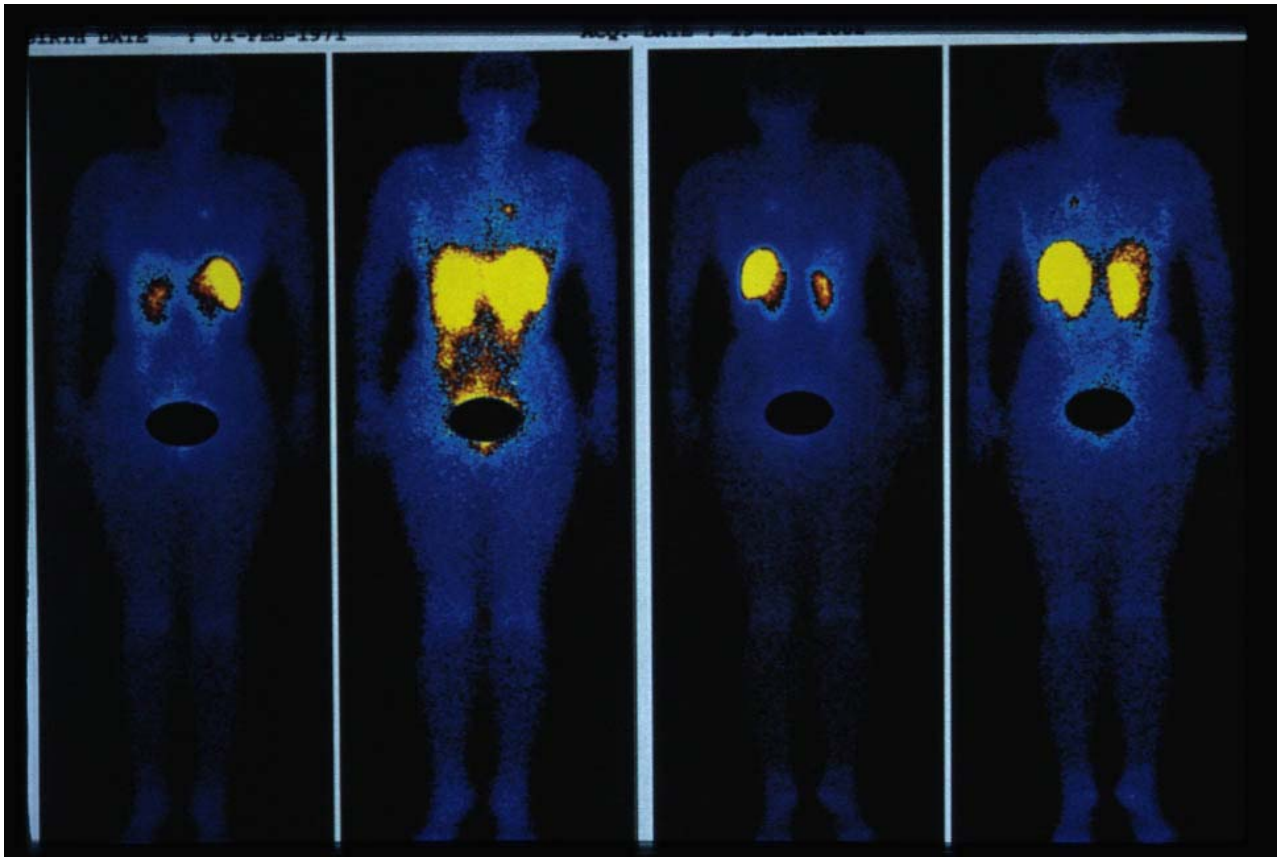


A, lower magnification; B, + control peptide; C & D, higher magnification



sstr2

(Cortesia Dr. Papotti, Università di Torino)



Protocollo **MICROCT-01**

TRATTAMENTO CON OCTREOTIDE LAR QUALE TERAPIA DI MANTENIMENTO IN PAZIENTI AFFETTI DA CARCINOMA POLMONARE A PICCOLE CELLULE

- Coordinatore** : Stefano Iacobelli
- Comitato scientifico di protocollo** : Pier Franco Conte, Luigi Dogliotti,
Stefano Iacobelli, Bruno Massidda
- Ricercatore responsabile** : Maria Teresa Martino
- Statistica e Data Management** : Nicola Tinari, Michele De Tursi
- Centro di coordinamento** : DataSense c/o Clinica Oncologica
Ospedale Clinicizzato SS. Annunziata
Università G. D'Annunzio, Chieti-Pescara

Disegno dello studio

Studio prospettico, multicentrico, randomizzato di fase III.

Dopo completamento del piano terapeutico di I linea (chemioterapia + radioterapia) i pazienti verranno randomizzati in uno dei due bracci di trattamento:

- A. Octreotide LAR 20 mg**
- B. Nessun trattamento**

Obiettivi dello studio

Obiettivo primario

Valutare la sopravvivenza libera da progressione (PFS) a 12 mesi;

Obiettivi secondari

Valutare il tempo di sopravvivenza globale (OS) a 24 mesi

Valutare la qualità di vita dei pazienti

Valutare la tollerabilità del trattamento