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The phase III study INTERCEPTOR in locally advanced head and neck cancer (LA-HNC). Preliminary safety report

A.Bacigalupo, S.Vecchio, L.Belgioia, R. Corvò, M.Merlano* on behalf of INTERCEPTOR study Group

IRCCS AOU San Martino IST- Genova; *ASO Santa Croce e Carle-Cuneo

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DICHIARAZIONE

Relatore: ALMALINA BACIGALUPO

Come da nuova regolamentazione della Commissione Nazionale per la Formazione Continua del Ministero della Salute, è richiesta la trasparenza delle fonti di finanziamento e dei rapporti con soggetti portatori di interessi commerciali in campo sanitario.

- Posizione di dipendente in aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Consulenza ad aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Fondi per la ricerca da aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Partecipazione ad Advisory Board **(NIENTE DA DICHIARARE))**
- Titolarietà di brevetti in compartecipazione ad aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Partecipazioni azionarie in aziende con interessi commerciali in campo sanitario **(NIENTE DA DICHIARARE)**
- Altro

Firma Almalina Bacigalupo

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INTERCEPTOR: CRT vsTPF ⇨ Cetuximab + RT in unresectable locally advanced SCCHN

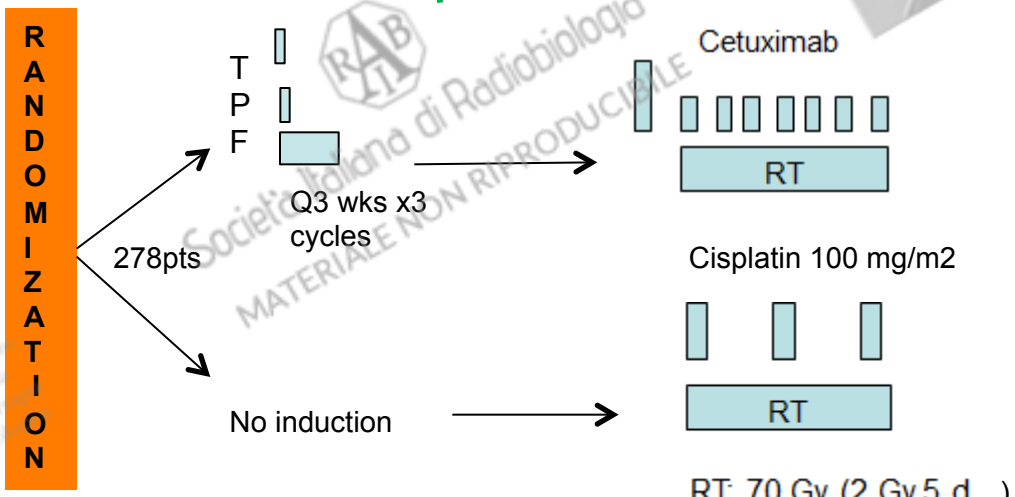
Open-label,randomized, multi-center Phase III trial
Lead investigator: M.Merlano
Gruppo Oncologico del Nord-Ovest

This study is currently recruiting

Inclusion criteria

SCCHN unsuitable for surgery
Stage III-IV

PS <2



Primary endpoint: OS (5yr)
Secondary endpoint include: PFS,LRC, RR,safety (all 5yr)

ClinicalTrials.gov Identifier: NCT00999700

TPF=docetaxel 75mg/m2 D1+cisplatin 75mg/m2 D1 + 5-FU 750mg/m2 D1-4

Recruiters Centres:

- *ASL-2 Osp S.Paolo Savona*
- *AOU Città della Salute e della Scienza Torino*
- *Ospedale ASL 3 Micone Sestri Ponente- Villa Scassi Genova*
- *Ospedale SS. Antonio e Biagio e Arrigo Alessandria*
- *AUSL Valle D'Aosta*
- *Ospedali Galliera Genova*
- *Istituto Nazionale Tumori Milano*
- *Policlinico Sant'Orsola-Malpighi Bologna*
- *IRCCS CROB Rionero in Vulture*
- *Ospedale Maggiore Parma*
- *Ospedale S.Croce Fano*
- *Policlinico Modena*
- *San Filippo Neri Roma*
- *IRCCS Santa Maria Nuova Reggio Emilia*
- *ASO S Croce e Carle-Cuneo*
- *IRCCS San Martino-IST Genova*

The INTERCEPTOR Trial

EUDRACT 2009-013402-14

Population (inclusion criteria):

1. Hystollogically confirmed SCC
2. Primary tumor in oral cavity, oropharynx, hypopharynx, larynx
3. Naïve pts
4. Stage III-IV
5. ECOG P.S. < 2
6. "unresectable" (technically unresectable, or requiring major demolitive surgery with low probability of cure, or refusal of surgical approach by the pt)
7. Adequate renal, liver, bone marrow and cardiological functions
8. Geographical accessibility
9. Signed informed consent

Pre-Treatment procedures

1. Complete physical examination
2. Dental evaluation
3. Nutritional evaluation
4. Analysis of the social and family environment

Statistic

1. Primary end-point: overall survival (5y):
2. Secondary end-points (5y):
    1. Toxicity
    2. L-R control
    3. Disease free survival
    4. Response rate
3. Sample 278 pts

Accrual (22 settembre 2016): 275/278 pts

MAJOR PATIENTS CHARACTERISTICS (242 pts)

1. Male/Female 199/43
2. Median Age 64 (35 -79)
3. Primary Site
   1. Oral Cavity 28
   2. Oropharynx 119
   3. Hypopharynx 64
   4. Larynx 31
4. STAGE III/IV 48/194
5. Smoking >10 pack/year 213 (88%)

PRELIMARY SAFETY ANALYSIS

Patients considered: 170

(treatment completed; data collection completed)

Distribution by treatment arm: ARM A = 85 ARM B = 85

Male/female by treatment arm: ARM A = 70/15 ARM B = 66/19

- **Toxicities considered are those causing at least 1 grade III in one patient.**
- **Toxicities considered for this safety analysis are reported as the worst grade observed during treatment in each patient**
- **Toxicities are graded according to the NCI-CTC version 3.0**

Toxicity	ARM A: Induction + BioRT		ARM B ChemoRT		X^2 test P
	G1 - G2	G3 - G4	G1 - G2	G3 - G4	
Leukopenia	23	8	33	6	0.27
* neutropenia	15	18	23	7	0.011
anaemia	61	2	54	3	0.9
platelets	20	0	12	1	0.82
stomatitis	41	32	40	24	0.45
Weight loss	35	2	37	2	0.21
*Radio dermatitis	45	15	47	3	0.007
Dysphagia	25	11	20	15	0.28
Death within 3 months	1		7		0.071

Conclusions

- Overall the two treatment arms show similar toxicity profiles.
- Only neutropenia and radio-dermatitis are significantly different between treatment A and B, both favouring arm B.
- The excess of neutropenia in Arm A is entirely due to the induction phase.
- There is a trend favouring Arm A in “death within 3 months”
- The study is ongoing

GORTEC 2007-02: CRT vs TPF ⇨ Cetuximab + RT
In unresectable locally advanced SCCHN

Open-label,randomized, multi-center Phase III trial
Investigator:L Geoffrois
Groupe Oncologie Radiotherapie Tete et Cou (GORTEC)

ClinicalTrials.gov Identifier: NCT01233843

Inclusion criteria

Inoperable SCCHN (hypopharynx, larynx, oral cavity, oropharynx)

Stage IV
T2-4, N2b-c or N3 M0

PS 0-1

RANDOMIZATION

370pts
2009-2013

T
P
F

Q3 wks x3 cycles

Cetuximab

RT

ARM B

Carboplatin 70mg/m2+5-FU 600mg/m2,d1-4

No INDUCTION

RT

ARM A

RT: 70 Gy (2 Gy,5 d per wk for 7 wks

Primary endpoint: PFS-14%improvement at 2 years
Secondary endpoint include: OS,LRC,distant metastasis, safety
HPV analysis

TPF=docetaxel 75mg/m2 D1+cisplatin 75mg/m2 D1 + 5-FU 750mg/m2 D1-5

TTCC- 2007-01: TPF ⇨ CRT or Cetuximab + RT In unresectable locally advanced SCCHN

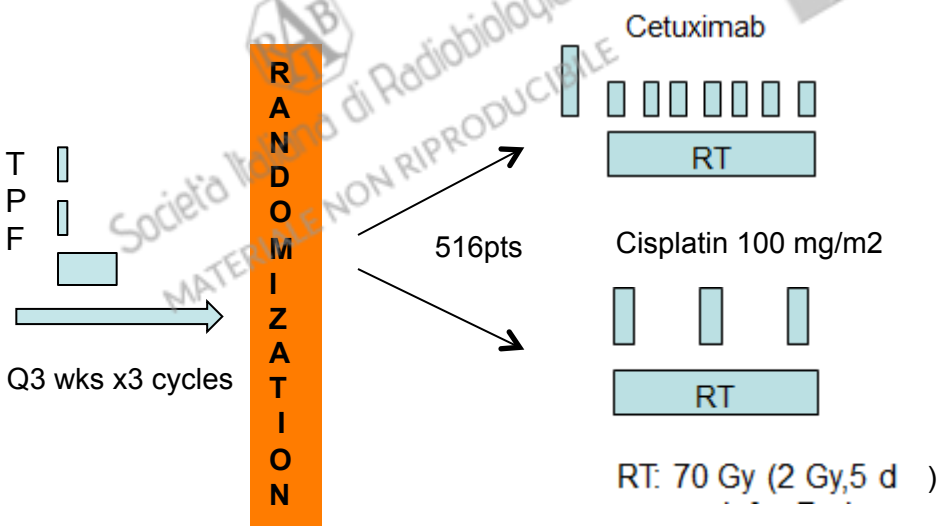
Open-label,randomized, multi-center Phase III trial
Investigator: R.Hitt, JJ Cruz
Gropo Espanol Tratamiento de Tumores de Cabeza y Cuello

Inclusion criteria

Inoperable hypopharynx, larynx, oral cavity, oropharynx)

Stage III-IV
T2-4, N2b-c or N3 M0

PS 0-1



Primary endpoint: OS- (3 years, noninferiority)
Secondary endpoint include: 2 yr DFS,OS, 1-3yr LRC, safety

TPF=docetaxel 75mg/m2 D1+cisplatin 75mg/m2 D1 + 5-FU 750mg/m2 D1-4

ClinicalTrials.gov Identifier: NCT00716391

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Gruppo Oncologico Nord Ovest

Azienda Ospedaliera S. Croce e Carle di Cuneo

INTERCEPTOR TRIAL

***IN**duction chemo**T**h**ER**apy followed by **CE**tuximab **P**lus defini**T**ive radi**O**the**R**apy versus radiation plus cisplatin*

Grazie per l'attenzione !

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