



# **Censimento Studi Clinici Rete Oncologica del Piemonte e della Valle d'Aosta – Carcinoma della mammella Filippo Montemurro**

Divisione di Oncologia Medica 1  
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# Aims of this analysis

- ❑ To cross check the repertoire of ongoing clinical trials at Centers of the Rete Oncologica del Piemonte e della Valle d'Aosta with the areas of research interest in breast cancer
  - To identify areas where research initiatives are lacking
- ❑ To elaborate strategies to boost referral to centers with ongoing clinical trials

# Areas of clinical research interest in breast cancer

- ❑ Unmet medical needs
  - Triple negative breast cancer
  - Hormone receptor positive/endocrine resistant
  - HER2-positive, trastuzumab and lapatinib resistant
- ❑ New drugs or combinations, new surgical and radiotherapeutic approaches
- ❑ Optimization of current treatments
  - Cost reducing strategies
  - Toxicity-reducing strategies
- ❑ Translational studies (including a better understanding on how drugs work)
- ❑ Optimization of multidisciplinary management
- ❑ Follow-up



# Methods

- ❑ After a few attempts at contacting each single Institution to get complete information, we decided to search on the Osservatorio Nazionale Studi clinici.

# Osservatorio Nazionale Studi Clinici



# List of Ongoing Trials

## SIGLA PROTOCOLLO

IBCSG 32-05  
IBIS 1 (studio intergruppo)  
Protocollo MULTICENTRICO CT NEOADIUVANTE 1  
Protocollo MULTICENTRICO CT NEOADIUVANTE 2  
HER2 POSITIVO  
L00070 IN 308 B0  
GIM8 OVER  
EGF 111438  
NAVELBINA-XELODA  
GIM 7  
bHERt2  
LAP112620  
ML19884  
EMILIA (BO21977 - TDM4370g)  
PHEREXA

## SIGLA PROTOCOLLO

TIPICALL  
VNBCAPTAX  
VNBCAPEPI  
VNBCAP  
MET/TEST1106  
WT1  
CFEM345D2411  
HERLAP  
SHORT-HER  
TAM-01  
DOUBLE  
SOLE  
IBCSG 34-05/SWOG 0230

28 trials clinici



# Details of clinical trials for early breast cancer

Patients subset	Therapeutic setting	Protocol Code	Randomized	Main intervention
<b>EBC HER2 positive</b>	ADJUVANT	ShortHER	Yes	Short vs long Trastuzumab Duration
	NEOADJUVANT	FEC→TH	No	Trastuzumab concomitant with paclitaxel
<b>EBC HR+</b>	ADJUVANT	CFEM345D2411	Yes	Anastrozole vs Letrozole
		DOUBLE	Yes	5y nsAI vs 2-3y nsAI → 2-3y sAI
		SOLE	Yes	Continuous vs Intermittent extended letrozole
		GIM3-FATA	Yes	AIs vs each other, upfront vs early switch
		IBIS 1	No	Tam + navelbine, low risk ER+
<b>EBC unfit for chemo.</b>	ADJUVANT	IBCSG 32-05	No	Liposomal doxo for unfit patients
<b>EBC NOS</b>	ADJUVANT	MET/TEST1106	No	Metformin to reduce testosterone levels
		IBCSG 34-05/SWOG 0230		Ovarian protection with LH-RH analogues
	NEOADJUVANT	NEOADIUVANTE SAPINO	No	Platform for biomarkers discovery
		WT1		Antigen specific immunotherapy
		ML19884		Bevacizumab added to CT in inflammatory BC
		IBCSG 34-05/SWOG 0230		Ovarian protection with LH-RH analogues
<b>DCIS</b>	ADJUVANT	TAM-01		Low dose tamoxifen



# Details of clinical trials for metastatic disease

Patients subset	Therapeutic setting	Protocol Code	Randomized	Main intervention
<b>MBC, HER2 +</b>	1st line, low tumor burden	HERLAP	Yes	Single agent Lapatinib or Trastuzumab
	CNS metastases	bHERt2	No	Trastuzumab + concomitant WBR
	Trastuzumab resistant	LAP112620	Yes	Lapatinib + capecitabine or vinorelbine
		PHEREXA	Yes	Trastuzumab-Capecitabine +/- Pertuzumab
		EGF 111438	Yes	Capecitabine + Lapatinib or Trastuzumab
		CAUY	No	Anti HSP90
<b>MBC, HER2+/ER+</b>	First line	TIPICALL	Yes	Lapatinib + endocrine or chemotherapy
<b>MBC, HER2-/ER+</b>	Previous AI	GIM8-OVER	Yes	Fulvestrant +/- AI +/- Lapatinib
<b>MBC, HER2-</b>	First Line	L00070 IN 308 B0	Yes	Vinflunine
	First line, maintenance	Navelbine-Xeloda	No	Prolonged administration in responding patients

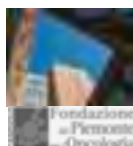




# Centres with active studies

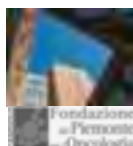
City	ISTITUZIONE	N
TORINO	AZIENDA OSPEDALIERA OIRM/S. ANNA DI TORINO	10
TORINO	A.O.U.S. GIOVANNI BATTISTA - MOLINETTE	9
CANDIOLO	IRCC CANDIOLO	7
CUNEO	AZIENDA OSPEDALIERA S. CROCE E CARLE	5
NOVARA	A.O. UNIVERSITARIA MAGGIORE DELLA CARITA'	4
BIELLA	OSPEDALE DEGLI INFERMI	4
ORBASSANO	A.O.U. S. LUIGI GONZAGA DI ORBASSANO	3
TORINO	PRESIDIO SANITARIO GRADENIGO	3
TORINO	OSPEDALE EVANGELICO VALDESE	3
TORTONA	OSPEDALE SS. ANTONIO E MARGHERITA DI TORTONA	2
TORINO	OSPEDALE MAURIZIANO	2
ALBA	OSPEDALE CIVICO SAN LAZZARO	2
IVREA	OSPEDALE CIVILE DI IVREA	2
ASTI	OSPEDALE CARDINALE GUGLIELMO MASSAIA	1
ALESSANDRIA	OSPEDALE CIVILE SS. ANTONIO E BIAGIO	1
AOSTA	OSPEDALE GENERALE REGIONALE	1
CASALE MONFERRATO	OSPEDALE S.SPIRITO	1
MONDOVI'	OSPEDALE CIVILE DI MONDOVI'	1
VERBANO-CUSIO-OSSOLA	OSPEDALE CASTELLI DI VERBANIA	1
PINEROLO	OSPEDALE CIVILE DI PINEROLO	1
MONCALIERI	OSPEDALE SANTA CROCE DI MONCALIERI	1

**Divisione di Oncologia Medica 1, IRCC Candiolo**



# Where?

NUMERO PROTOCOLLO	ISTITUZIONE
hHEB12	IRCC CANDIOLO
	A.O.U.S. GIOVANNI BATTISTA - MOLINETTE
CADY	IRCC CANDIOLO
CDEM34502413	OSPEDALE DEGLI INFERMI
EXCUMI	A.O. UNIVERSITARIA MAGGIORE DELLA CARITA'
	PRESIDIO SANITARIO GRADENIGO
	AZIENDA OSPEDALIERA OIRM/S. ANNA DI TORINO
	A.O.U.S. GIOVANNI BATTISTA - MOLINETTE
	OSPEDALE CIVILE SS. ANTONIO E BIAGIO
	OSPEDALE S.SPIRITO
	OSPEDALE SS. ANTONIO E MARGHERITA DI TORTONA
	OSPEDALE CIVILE DI MONDOVI'
	AZIENDA OSPEDALIERA S. CROCE E CARLE
	OSPEDALE CARDINALE GUGLIELMO MASSAIA



# Where?

NUMERO PROTOCOLLO	ISTITUZIONE
h11112	IRCC CANDIOLO
	A.O.U.S. GIOVANNI BATTISTA - MOLINETTE
CADY	IRCC CANDIOLO
CDEM34502413	OSPEDALE DEGLI INFERMI
EX00518	A.O. UNIVERSITARIA MAGGIORE DELLA CARITA'
	PRESIDIO SANITARIO GRADENIGO
	AZIENDA OSPEDALIERA OIRM/S. ANNA DI TORINO
	A.O.U.S. GIOVANNI BATTISTA - MOLINETTE
	OSPEDALE CIVILE SS. ANTONIO E BIAGIO
	OSPEDALE S.SPIRITO
	OSPEDALE SS. ANTONIO E MARGHERITA DI TORTONA
	OSPEDALE CIVILE DI MONDOVI'
	AZIENDA OSPEDALIERA S. CROCE E CARLE
	OSPEDALE CARDINALE GUGLIELMO MASSAIA



# Where?

NUMERO PROTOCOLLO	ISTITUZIONE
EGF 111838	A.O. UNIVERSITARIA MAGGIORE DELLA CARITA'
GINET	IRCC CANDIOLO
GINE OVER	A.O. UNIVERSITARIA MAGGIORE DELLA CARITA'
	A.O.U.S. GIOVANNI BATTISTA - MOLINETTE
	IRCC CANDIOLO
	OSPEDALE MAURIZIANO
	AZIENDA OSPEDALIERA OIRM/S. ANNA DI TORINO
	OSPEDALE EVANGELICO VALDESE
HERAP	OSPEDALE CIVICO SAN LAZZARO
	IRCC CANDIOLO
	A.O.U.S. GIOVANNI BATTISTA - MOLINETTE
	A.O.U. S. LUIGI GONZAGA DI ORBASSANO
	OSPEDALE EVANGELICO VALDESE
	PRESIDIO SANITARIO GRADENIGO
	AZIENDA OSPEDALIERA OIRM/S. ANNA DI TORINO
	AZIENDA OSPEDALIERA S. CROCE E CARLE



# Unmet demands



Unmet medical needs	Number of studies	Participating Institutions
Triple negative breast cancer	0	0
Hormone receptor positive/endocrine resistant	1	6
HER2-positive, trastuzumab and lapatinib resistant	4	4
New drugs or combinations, new surgical and radiotherapeutic approaches	2	2
Optimization of current treatments	1	
Cost reducing strategies	1	
Toxicity-reducing strategies	1	
Translational studies (including a better understanding on how drugs work)	1	
Optimization of multidisciplinary management	0	0
Follow-up	0	0



# Future directions

- ❑ To set up a system that allows real time update of study status (enrolling, closed to accrual)
- ❑ To organize clinical trials information into an online searchable database that will allow a physician to rapidly identify if a patients with a particular clinical situation is suitable for referral to an Institution with a relevant ongoing clinical trial.

