

Update Ongoing Trials BS BMT-Unit



Ongoing non-sponsored studies (2020)

Study	WP	Field	Responsible	Pt	Publication	Submitted EC	EC approval
GIMS	REL -Passamonti	LMC	Polverelli	7	Blood res 2020	Yes	13/Nov/2017
MF-2001	MF-Net	MPN	Polverelli	40	BJH 2020; project ongoing	No	/
RUX-MF-DFX	MF-Net	MPN	Polverelli	2	Awaiting	Yes	06/Jul/2017
RUXOREL	REL -Passamonti	MPN	Polverelli	22	Blood Adv2019; ongoing	Yes	30/Jan/2018
PV-real life	PV-Net	MPN	Polverelli	10	awaiting	Yes	28/May/2020
MVs-IN-MPS	MF-Net	MPN	Polverelli	2	awaiting	Yes	22/Jul/2020
PTCy vs ATG in MF	CMWP	2020	Polverelli	11	awaiting	No	/
FT vs FB in MF	CMWP	2020	Polverelli	8	awaiting	No	/

Ongoing non-sponsored studies (2020)

Studies	Submitted EC	EC approval	Enrolled patients	Published abstract	Published full paper
Allogenic SCT in elderly: BS Study	Yes	22/03/2019	50	No	No
OPTkIMA Study 1013	Yes	31/03/2015	26 centers – 220 pt	Yes	Yes
Modulen-TGF- β 2	Yes	27/02/2020	40	No	No
MicrobiomAML	Yes	11/Jan/2019	1	No	No
Prospective study on the psycho-social well-being of the pt candidate for HSCT and his caregiver	Yes	Jan/2020	33 (15♀;18♂) and 20 caregiver	No	No

Allogenic SCT in elderly: BS Study

Allogenic stem cell transplantation (ALLO-SCT) in elderly: a prospective hemato-geriatric joint evaluation – ALLO-ELD study

Type of study:

retrospective observational

Primary objective:

Description of the patients population. This objective will particularly focus on the changing, over the years, of the clinical and hematological characteristics of elderly patients submitted to allo-SCT

PI: Prof Michele Malagola

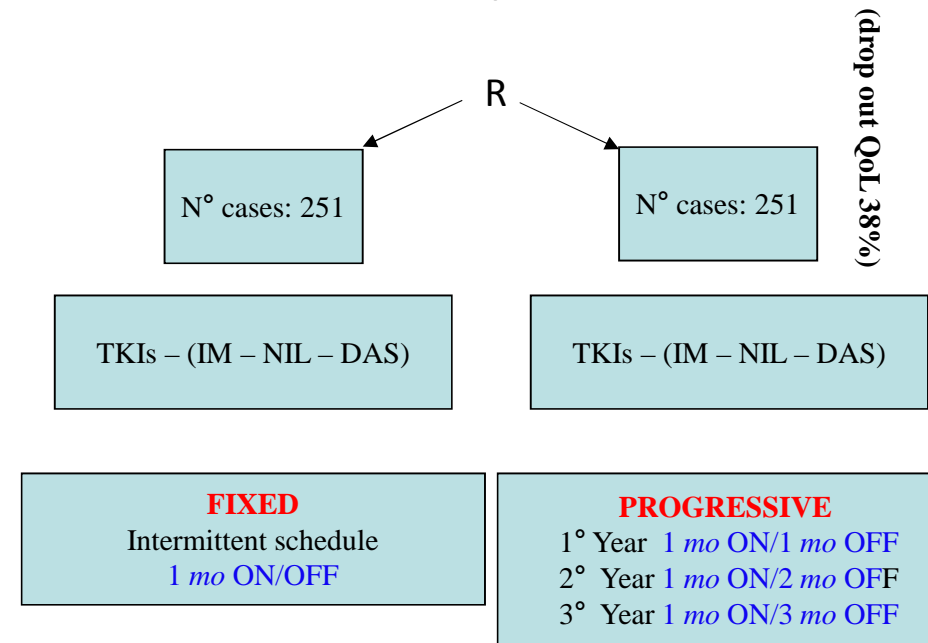
OPTkIMA Study 1013 - OPTimize TKIs Multiple Approaches

Phase-III randomized study to Optimize TKIs Multiple Approaches - (OPTkIMA) – and quality of life (QoL) in elderly patients (≥ 60 years) with Ph+ chronic myeloid leukemia (CML) and MR3.0/MR4.0 stable molecular response

Phase: III

Primary objective:

To investigate whether “progressive” intermittent administration of TKIs (experimental arm) provides better outcomes than “fixed” intermittent administration of TKIs (control arm) in the following QoL scales: Fatigue, Physical Functioning and Global Health Status/QoL (outcome measure: EORTC QLQ-C30), Impact on Daily Life and Symptom Burden (outcome measure: EORTC CML-24), Burden of Illness (outcome measure: EORTC QLQ-ELD14).



PI: Prof Domenico Russo

OPTkIMA Study 1013 - OPTimize TKIs Multiple Approaches

632. CHRONIC MYELOID LEUKEMIA: THERAPY: POSTER III | NOVEMBER 29, 2018

First Interim Report of the Italian Multicentric Phase-III Randomized Study to Optimize TKIs Multiple Approaches - (OPTkIMA) in Elderly Patients (older than 60 years) with Ph+ Chronic Myeloid Leukemia (CML) and MR3.0/ MR4.0 Stable Molecular Response

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ORIGINAL RESEARCH

Cancer Medicine | WILEY

Molecular response and quality of life in chronic myeloid leukemia patients treated with intermittent TKIs: First interim analysis of OPTkIMA study

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Modulen – TGF-β2

Nutritional support with TGF-β2 enriched polymeric formulation in patients undergoing haematopoietic stem cell transplantation (HSCT)

Type of study:

Interventional perspective

Primary objective:

Evaluation of clinical and nutritional impact of taking the formulation enriched with TGF-β2 on the incidence of malnutrition at +28 days after transplantation in patient undergoing allo-SCT

PI: Dr Enrico Morello

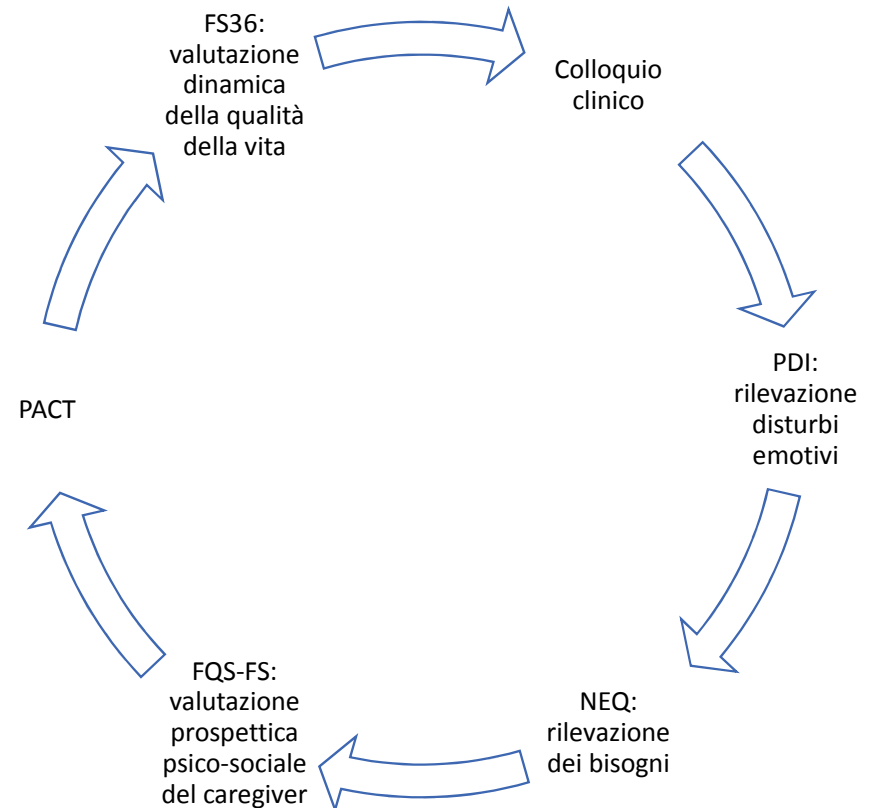
Prospective study on the psycho-social well-being of the pt candidate for HSCT and his caregiver

Type of study:

Prospective

Primary objective:

Dynamic detection of psychological distress through a systemic screening of the emotional distress and unexpressed needs of patients who are candidate for HSCT, wich allows the identification of all patients who need to be a psychological interventions and expansion of the transplant guide



PI: Dr Elsa Cavagna

MicrobiomAML

Prospective biological, non pharmacological, no-profit study for NGS evaluation of microbiome in Acute Myeloid Leukemia patients from diagnosis to one month after allogenic Stem Cell Transplantation

Type of study:

Prospective

Primary objective:

Evaluate by NGS the microbiota of AML patients from diagnosis to allo-SCT

Fecal sampling will be collected as following



PI: Dr Enrico Morello