SERVIZIO SANITARIO REGIONALE
EMILIA - ROMAGNA
Istituto Ortopedico Rizzoli di Bologna
Istituto di Ricovero e Cura a Carattere Scientifico

"Chemotherapy-induced necrosis in Ewing sarcoma: which is the best scoring tool?"

Study code	**EW-score**
Sponsor's Name and Address:	Istituto Ortopedico Rizzoli Via di Barbiano 1/10 40136 Bologna Italy
Study Number/Version/Date:	Vers 1.0 08 Mar 2019
Coordinating Center:	IRCCS Istituto Ortopedico Rizzoli Pathology Unit Via Pupilli 1 40136 Bologna, Italy
Coordinating Investigator and address:	Alberto Righi MD Phone: 051-6366.665 Email: alberto.righi@ior.it
Scientific/Medical study responsible and developer	Alberto Righi MD
Methodology:	Retrospective study (Single insitution case series review of clinical data)
Type:	Academic
Founding:	None
Principal Investigator Signature	I confirm that I've read this protocol and I accept to run the study in compliance with what is stated in the protocol and with the ICh-GCP and all applicable law Alberto Righi MD Firma _____

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BACKGROUND

Ewing sarcoma, commonly bearing a pathognomonic *EWS-FL1* translocation, is the second most common bone malignancy in children and adolescents, with an annual incidence of 200–500 cases in the United States and of 120-150 cases in Italy [1,2]. With advances in multidisciplinary care, 5-year survival rates for pediatric Ewing sarcoma patients have improved from 50% during the period from 1983–1990 to 70% during the period from 2004–2016 [1-3]. Prolonged disease-free survival is achieved in the majority of patients with localized Ewing sarcoma after treatment with multiagent chemotherapy and primary tumor control [3]. The best predictive factor is histologically determined chemotherapy-induced necrosis assessed in resected primary tumors, that has allowed to identify patients who are candidates for more intensive or novel therapies [3-6]. The good and poor responder patients to neo-adjuvant chemotherapy has been defined to different systems published in literature: true Percentage, Huvos System and Bologna System [4-7].

OBJECTIVE OF THE STUDY

The aim of the present study is to evaluate which is the best scoring tool to determine the histological response to chemotherapy in localized Ewing sarcoma of bone.

The study will exam all the different systems to evaluate the histological necrosis after neo-adjuvant chemotherapy in all patients with localized Ewing sarcomas of bone surgically treated between 1982 and 2012.

STUDY DESIGN

This is single institution cases series review of histological and clinical data

POPULATION

Inclusion criteria

1) Male and female patients surgically treated at Rizzoli Institute from 01 Jan 1982 to 31 Dic 2012
2) Patients with diagnosis of Ewing sarcoma of bone who have had neo-adjuvant chemotherapy
3) Diagnosis of Ewing sarcoma localized

Exclusion criteria

1. Metastatic disease at presentation
2. Soft tissue origin
3. Radiotherapy before surgery

The study will include male and female patients without limit of age

MATERIAL AND METHODS

We will retrieve from the database of the Rizzoli institute all the cases with a histological diagnosis of Ewing sarcoma from 01 Jan 1982 to 31 Dic 2012.

We aspect to find approximately 500 cases.

We will review all the medical records, and histological data of these cases.

STATISTICS

To the case series will be applied a descriptive statistic.

DATA COLLECTION

Clinical data will be retrieved by patient charts.

A protocol-specific CRF reporting the results of the review will be provided.

A CRF is required and should be completed for each included subject.

ETHICS AND QUALITY ASSURANCE

The clinical trial protocol and its documents will be sent before initiating the study to the competent Authorities and Ethics Committees of each participating country for its approval.

The responsible investigator will ensure that this study is conducted in agreement with either the most updated Declaration of Helsinki and all the international and local laws that apply to clinical trials and to patient protection.

The protocol has been written, and the study will be conducted according to the principles of the ICH Harmonized Tripartite Guideline for Good Clinical Practice
(ref: http://www.emea.eu.int/pdfs/human/ich/013595en.pdf).

INFORMED CONSENT

For Scientific Institute for Research and Healthcare (IRCCS) informed consent form to the processing of personal data is not applicable as for the Article 110 bis, paragraph 4 of the New Privacy Code (GDPR) regarding the use of clinical activity data collected for research purposes

CONFIDENTIALITY

In order to ensure confidentiality of clinical trial data as disposed the national and European applicable regulation, data will be only accessible for the trial Sponsor and its designees, for monitoring/auditing procedures, the Investigator and collaborators, the Ethics Committee of each corresponding site and the Health Authority.

Investigator and the Institution will allow access to data and source documentation for monitoring, auditing, Ethic Committee revision and inspections of Health Authority, but maintaining at all times subject personal data confidentiality as specified in the "Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995".

The Investigator must guarantee that patient anonymity is kept at all times and their identity must be protected from unauthorized persons and institutions.

All patients included in the study will be identified with a numeric code, so that no identifiable personal data will be collected (pseudo anonymization)

The Investigator must have and conserve a patients' inclusion registry where it figures the personal data of the patient: name, surname, address and corresponding identification code into the study, this register will be kept on the Investigator File.

PUBBLICATION OF RESULTS

The results from this study will be published or shown at scientific conferences.

The final publication of the study results will be written by the Principal Investigator.

SPONSOR ROLE AND RESPONSIBILITY

The sponsor is the sole owner of the data and is responsible of all the clinical trial activities from study design, development, data collection, management, analysis, interpretation of data, writing and the decision to submit the report for publication written by the Principal Investigator,

REFERENCES

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