INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Systematic Review on the Use of Biosimilars of Trastuzumab in Her-2+ Breast Cancer

Triantafyllidi, E[1]; Triantafyllidi, J[2].

Review question / Objective: **Are biosimilars of trastuzumab equivalent to trastuzumab originators in terms of safety, effectiveness, and economic evaluation?**
Eligibility criteria: **Only articles published in the English language were evaluated. The relevant literature was reviewed and the data of each study were recorded. All prospective and retrospective clinical studies were selected. All studies related to the efficacy and safety of trastuzumab in BC, were also selected regardless of the size of the sample. In all studies the following data were recorded: First author, year of publication, trial phase, number of patients, characteristics of the patients' population (first-line treatment, second-line treatment, neoadjuvant treatment etc.), histological type, median age, overall response rate (ORR), including both full response rate and partial response (%), median overall survival (OS) (in months), disease-free median survival and complications. In cases where multiple, overlapping publications from the same study were identified the most currently published study was included.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 July 2022 and was last updated on 12 July 2022 (registration number INPLASY202270067).

INTRODUCTION

Review question / Objective: **Are biosimilars of trastuzumab equivalent to trastuzumab originators in terms of safety, effectiveness, and economic evaluation?**

Condition being studied: **HER2+ breast cancer.**

METHODS

Search strategy: **MEDLINE from January 2010 to January 2022.**

Participant or population: **Patients with early or metastatic HER2+ breast cancer.**

Intervention: **Trastuzumab biosimilars.**

Comparator: Trastuzumab originator.

Study designs to be included: RCT.

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Information sources: MEDLINE.

Main outcome(s): The results of this systematic review showed that the approved and investigated biosimilars have the same efficacy and safety as trastuzumab. The pharmacological and clinical characteristics of both formulations (biosimilar and reference) are comparable. A large number of biosimilars have been approved so far, with many others biosimilars are in the process of being tested for safety and efficacy. The result of this explosion in biosimilar growth is expected to save hundreds of thousands of lives worldwide each year, as an increasing number of patients will be able to access these modern treatments. It is encouraging that both the US FDA and Europe EMA are adopting biosimilars with accelerating procedures but which do not go beyond the acceptable scientific safety standards for their approval. The development of trastuzumab biosimilars for subcutaneous administration (as is already the case with the reference medicine) will be a step forward in the treatment of patients as a large number of them are expected to choose this route of administration. It is also expected that the hesitation of oncologists to choose biosimilar instead of the reference drug will be eliminated in the near future. Finally, the "conquest" of a large part of the drug market share by the biosimilars will lead to the reduction of pharmaceutical costs and the recovery of insurance systems, while incomparably more patients will have access to these treatments.

Quality assessment / Risk of bias analysis: No bias was detected, RCTs are included.

Strategy of data synthesis: No meta-analysis planned.

Subgroup analysis: No meta-analysis planned.

Sensitivity analysis: No sensitivity analysis planned.

Language: English.

Country(ies) involved: Greece.

Keywords: Breast cancer, Trastuzumab, Monoclonal antibodies, Biosimilars, Treatment, Cost.

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