

COMBACTE-CARE

Combatting Bacterial resistance in Europe- Carbapenem-Resistance

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COMBACTE-CARE (Combatting Bacterial Resistance in Europe-Carbapenem-Resistance), as part of the New Drugs 4 Bad Bugs (ND4BB) framework consists of highly innovative studies and activities related to the treatment of patients with infections caused by carbapenem-resistant Enterobacteriaceae (CRE).

Infections due to multi-drug resistant CRE are rapidly increasing as an immediate public health threat that requires urgent and aggressive action as recently recognized by the World Health Organization. CRE usually express resistance to most available antibiotics, leaving few available options for therapy. In addition, the epidemiology of CRE is characterized by large heterogeneity in genotypes and phenotypes, seriously hampering the rapid detection of CRE.

This unique collaboration addresses the need for greater understanding of the clinical management and outcomes of CRE infections and also makes a significant contribution to the development of ATM-AVI for the treatment of patients with serious infections caused by Gram-negative bacteria for which currently there are limited or no treatment options.

University Medical Center Utrecht is the project's managing entity and AstraZeneca is the coordinator.

PROJECT OUTLINE

The EUR 83 million COMBACTE-CARE projects aims – during the 5-year project time - to understand how patients with CRE infections are managed, with a focus on best available treatment and clinical outcomes. The project will develop new tools to detect CRE and conduct clinical trials with Pfizer's antibiotic combination product Aztreonam-avibactam (ATM-AVI), in development for the treatment of serious infections due to metallo- β -lactamase producing Gram-negative pathogens, a difficult to treat sub-type of CRE infections.

COMBACTE-CARE Partners



ACTIVITIES

Now in its second year COMBACTE-CARE activities are progressing to combat the rapidly growing threat of infections caused by carbapenemase-producing bacteria in Europe.

Ongoing studies and trials of the COMBACTE-CARE consortium include:

- EURECA : A prospective observational study to assess the risk factors, clinical management and outcomes of hospitalized patients with serious infections caused by MDR-GNB. 31 of 49 selected EURECA sites are active. 409 patients of the 2000 patient target have been recruited.
- Microbiological studies to support the prospective observational, Phase II and Phase III studies
- Biomarker studies are making use of the study samples from the patient trials to optimize patient selection with poor outcome in future studies.
- REJUVENATE : A Phase II prospective, multicenter study, to determine the pharmacokinetics (PK), safety and tolerability of ATM-AVI in patients with a serious bacterial infection (complicated intra-abdominal infections). Active recruitment phase with 50% target achieved
- European component of a prospective, randomized, multicenter, assessor-blind, parallel group, comparative Phase III study to determine the efficacy, safety and tolerability of ATM-AVI for the treatment of serious infections due to metallo- β -lactamase producing Gram-negative pathogens.
- Preparations for this study are well advanced with the selection of study sites having started.

STUDY LOCATIONS

COMBACTE-CARE clinical trial activities are focused in experienced centers in Spain, France and Germany for REJUVENATE and with expansion into South-Eastern Europe for EURECA and the ATM-AVI phase III. The global ATM-AVI phase 3-study is currently being set up with AstraZeneca but will be transitioning to Pfizer. The trial is also funded by US Biomedical Advanced Research and Development Authority (BARDA).

COLLABORATION

The COMBACTE-CARE consortium brings together 18 European academic partners, 3 European Federation of Pharmaceutical Industries and Associations (EFPIA) partners from 10 European countries to closely collaborate on combatting carbapenem resistance. AstraZeneca, the Coordinator of the project, is in the process of transferring the project to Pfizer.

Efforts to develop novel antibiotics are hampered by a number of scientific and regulatory hurdles that cannot be easily tackled by any individual organization. The COMBACTE-CARE project closely collaborates with and further strengthens the clinical and laboratory networks CLIN-Net and LAB-Net of COMBACTE-NET, one of the first projects within the ND4BB program, that started in January 2013. The project is also part of a global collaboration with AstraZeneca and BARDA to develop the global Phase III ATM-AVI clinical trial.

COMBACTE-CARE researchers are widely considered to be global opinion leaders due to their expertise in executing clinical trials evaluating new (and established) antibiotics or anti-infective agents, antibiotic strategies and preventive measures against Healthcare-associated Infections (HAIs) as well as guiding antibiotic and infection prevention policies.

CONTACT INFORMATION

Unique in its scale, ambition, and its potential benefits for patients, public health and pharmaceutical research in Europe, the COMBACTE projects have the potential to become the powerhouse of anti microbial drug development in Europe that could serve as a standard for other groups. [Join us!](#)

Visit us at booth 29 in the exhibition hall.
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