

WELCOME TO THE REMAP-CAP NEWSLETTER:

Cysteamine edition

VOL6 27th April 2022



REMINDERS

- Please note the following when requesting access to Spiral/MACRO: Access to **Spiral** will allow you to screen, randomise and enter data for patients. Access to **MACRO** is used for 6 month follow up and data linkage.
- Please also remember that the platform inclusion and exclusion differ for pandemic vs non-pandemic domains. Please see page 4 for more information.
- Recordings of previous Webinars can be accessed here: WE4YOU – REMAPCAP. Any remaining question after the webinar can be sent to eu.remapcap@umcutrecht.nl
- Free of charge Vit C can be ordered via your Alliance account using PIP code **8042228**
- Free of charge Cysteamine can be provided on request
- All sites can activate as many pandemic and non pandemic domains as they wish, please contact us at ukremap-cap@icnarc.org for more information
- Please contact ukremap-cap@icnarc.org for all UK REMAP-CAP study based questions

Cysteamine Update from NovaBiotics

Co-administration of Cysteamine with Antibiotics:

Cysteamine has a number of properties which may be of therapeutic benefit as an intervention in CAP (all causes) including antibiotic potentiation (plus mucolytic anti-inflammatory, anti-virulence and antiviral effects). Cysteamine has broad antibiotic-potentiating activity, across multiple different classes against bacteria associated with pneumonia. Antibiotics should ideally be administered around the same time as cysteamine where this is convenient or fits around dosing interval, with exceptions regarding beta lactams as described in the pharmacy guide.

Cysteamine in non-COVID CAP:

Because of its antibiotic-potentiating and other potential benefits detailed above, cysteamine is unique as an intervention ideally suited to CAP of all causes and therefore all strata in the study - not solely COVID-19.

Cysteamine at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID):

The following two abstracts on the immunomodulatory and antibacterial potentiation properties of cysteamine in CAP have been accepted for presentation at this year's ECCMID congress on 23rd – 26th April. This is an opportunity for NovaBiotics Ltd to present new *in vitro* and *in vivo* data supporting cysteamines therapeutic utility in CAP of all causes at the conference.

- Abstract1: Glycine decarboxylase (GLDC) inhibition by cysteamine, a phase III clinical candidate intervention for community-acquired pneumonia (CAP), potentiates the host response to respiratory viruses, including SARS-CoV-2, via pyrimidine restriction
- Abstract2: Cysteamine, a phase III clinical candidate intervention for community-acquired pneumonia (CAP) improves antibiotic-mediated protection from death in *C. elegans* infected with antibiotic-resistant strains of bacteria commonly associated with pneumonia

Setting up the Cysteamine domain at your site

- Request the Cysteamine training Pack – email us at ukremap-cap@icnarc.org
- Complete the below documentation:
 - Cysteamine DSA choice page
 - Cysteamine training log for
Log and the Cysteamine inventory Log
 - Cysteamine shipping request form
- Confirm your site are able to complete the cysteamine accountability
- Confirm you have sufficient -20 freezer storage space for cysteamine stock
- Provide full pharmacy delivery details
- Provide confirmation of local approval for AM028, AM029 and AM032

PANDEMIC PLATFORM ELIGIBILITY CRITERIA

Inclusion

- Patient is 18 years or over
- COVID-19 is suspected by the treating clinician or has been confirmed by microbiological testing
- Microbiological testing for SARS-CoV-2 infection of upper or lower respiratory

Exclusion

- Death is deemed to be imminent or inevitable during the next 24 hours AND one or more of the patient, substitute decision maker or attending physician are not committed to full active treatment
- Admission to hospital over 14 days ago with acute COVID illness
- Expected to be discharged from hospital today or tomorrow
- Previous participation in this REMAP within the last 90 days

NON-PANDEMIC PLATFORM ELIGIBILITY CRITERIA

Inclusion

- Patient is 18 years or over
- **Admitted to ICU:**
 - For acute severe CAP within 48 hours of hospital admission
 - Has symptoms or signs or both that are consistent with lower respiratory tract infection (for example, acute onset of dyspnoea, cough, pleuritic chest pain)
 - Has radiological evidence of new onset infiltrate of infective origin (in patients with pre-existing radiological changes, evidence of new infiltrate)
- **Up to 48 hours after ICU admission patient is receiving organ support with one or more of:**
 - Non-invasive or invasive ventilatory support
 - Receiving infusion of vasopressor or inotropes or both

Exclusion

- **Healthcare-associated pneumonia:**
 - Prior to this illness, is known to have been an inpatient in any healthcare facility within the last 30 days
 - Resident of a nursing home or long-term care facility
 - Death is deemed to be imminent or inevitable during the next 24 hours AND one or more of the patient, substitute decision maker or attending physician are not committed to full active treatment.
- **Previous participation in this REMAP within the last 90 days.**



COVID-19

MILESTONES 2022



**ACTIVE PANDEMIC TREATMENT
DOMAINS**

Active on ICU only

- Vitamin C (REMAP-CAP Ascorbic Acid IMP supplied on request)
- Simvastatin
- Anticoagulation
- Cysteamine (Cysteamine bitartrate IMP supplied on request)

**ACTIVE NON-PANDEMIC TREATMENT
DOMAINS**

Active on ICU only

- Antibiotics
- Macrolide Duration (only in association with the antibiotic domain)
- Corticosteroid
- Vitamin C
- Cysteamine (Cysteamine bitartrate IMP supplied on request)

MONITORING

Onsite monitoring visits are now being booked in. Please do let us know if you would like to organize an onsite monitoring visit, close out visits or implement an extended pause at site.

CELEBRATE YOUR SUCCESS

So much has been achieved by the UK REMAP-CAP sites. THANK YOU EVERYONE for your continued SUPPORT. The evidence you are generating is already improving care for patients with COVID-19.

We'd also love to hear from you so please feel free to stay in touch with the REMAP-CAP family via our social media outlets.

We look forward to the time when we can celebrate your success together.



