

Treatment guidelines for hyperkalemia (potassium level > 5.0 mmol/L)

General principles

Patients will have their plasma (or serum) potassium checked by a local laboratory at every visit and no patient can be included with a plasma (or serum) potassium level >5.0mmol/L according to inclusion criteria. All patients not receiving study medication will be treated according to local guideline. All events of hyperkalemia must be recorded in the eCRF for all patients in the intervention group.

The follow plasma potassium levels (section 1 to section 3) has to view in proportion to a reference range of 3.6 to 4.6 mmol/ L (SD 0.08 mmol/ L). In case serum potassium levels are routinely used or another reference range are used the following must apply.

- Section 1: Potassium level > 0.4 and < 0.9 mmol/L above reference range.
- Section 2: Potassium level ≥ 0.9 and < 1.4 mmol/L above reference range.
- Section 3: Potassium level ≥ 1.4 mmol/L above reference range.

1 Plasma potassium level > 5.0 and < 5.5 mmol/L

1.1 Confirmation

Confirm potassium concentration in a non-haemolysed sample.

1.2 Change of dietary intake

Patients will be given advice to lower dietary intake of potassium and restriction of food/drinks with high potassium content. (e.g. fruit juice, melon, bananas etc.)

1.3 Review of medical treatment

Review of medical regimens for agents known to cause hyperkalemia (including over-the-counter medication). Consider reduction or discontinuation of these agents, *only if it is clinically acceptable.*

- Potassium supplements
- Non-Steroidal anti-inflammatory drugs (NSAIDs)
- Cyclo-oxygenase-2 (COX-2) inhibitors
- Trimethoprim
- Herbal supplements

1.4 Additional treatment

Consider reduction in ACE or ARB or increase in diuretics.

1.5 Follow-up

Repeat measurement of potassium within 5 days.

If potassium remains in the level of < 5.0 and >5.5 mmol/L regularly monitoring of plasma potassium to ensure stability should be done. (Suggested once monthly).

2 Plasma potassium level ≥ 5.5 and < 6.0 mmol/L

Apply all instruction listed in section 1 In addition:

2.1 Study medication

Temporarily discontinue study medication.

Evaluate continuation of the study medication after 10 days (according to section 1.5).

2.2 Additional treatment

Consider treatment with non-potassium sparing diuretics (or increased doses of ongoing treatment).

Consider treatment with natriumpolystyrenesulfonat.

Reduce treatment dose of ACE inhibitor or Angiotensin II receptor blocker (ARB)

2.3 Follow-up

Repeat measurement of potassium within 3 days.

2.4 Plasma potassium level ≥ 6.0 mmol/L

Apply all instruction listed in section 1.2. In addition:

2.5 Study medication

Immediately discontinue study medication.

2.6 Follow-up

Urgently evaluate the patient and treat hyperkalemia as clinically indicated.

3 Continuation of study medication

If the plasma potassium is < 5.5 mmol/L the patient can continue taking study medication.

Patients who continue study medication after temporary discontinuation of study medication must have the potassium measured according to section 1.5

In a patient who has experienced a plasma potassium of ≥ 6.0 mmol/L, in whom the potassium fails to decrease to ≤ 5.5 mmol/L after the procedures described above have been tried, the study medication, must be discontinued permanently and it should be recorded in the eCRF.

In case of repeated episodes of confirmed hyperkalemia after the attempt to re-start study medication following discontinuation the study medication must be discontinued permanently and it should be recorded in the eCRF and to the IWRS.

Patients, who discontinue the study medication, will remain in the study and be followed for the full duration of the study.