Figure 1:

Excluded (n = 196):
- Inclusion criteria not met (n = 180)
- Refused to participate (n = 6)
- Other reasons (n = 7)

Allocated to C.E.R.A. QW
0.7, 1.4, or 2.1 µg/kg
(n = 109)

C.E.R.A. QW
0.7 µg/kg
(n = 36)

C.E.R.A. QW
1.4 µg/kg
(n = 37)

C.E.R.A. QW
2.1 µg/kg
(n = 37)

Included in ITT/safety analysis
(n = 36)

Included in ITT/safety analysis
(n = 37)

Included in ITT/safety analysis
(n = 37)

Discontinued
(n = 5):
- 3 AEs;
- 1 death;
- 1 treatment refusal;
- 1 investigator decision.

Discontinued
(n = 5):
- 2 AEs;
- 2 deaths;
- 1 treatment refusal;
- 1 failure to return.

Discontinued
(n = 35)*

C.E.R.A. Q3W
2.1 µg/kg
(n = 37)

C.E.R.A. Q3W
4.2 µg/kg
(n = 37)

C.E.R.A. Q3W
6.3 µg/kg
(n = 35)

Included in ITT/safety analysis
(n = 37)

Included in ITT/safety analysis
(n = 34)*

Included in ITT/safety analysis
(n = 37)

Discontinued
(n = 8):
- 2 AEs;
- 4 deaths;
- 1 treatment refusal;
- 1 failure to return.

Discontinued
(n = 8):
- 3 deaths;
- 1 treatment refusal.

Discontinued
(n = 8):
- 3 deaths;
- 3 AEs;
- 1 investigator error.

AEs: adverse events.
ITT: intent to treat.
QW: once weekly.
Q3W: once every 3 weeks.
*One patient in the C.E.R.A. 2.1 µg/kg QW group, three patients in the 2.1 µg/kg Q3W group and one patient in the 6.3 µg/kg Q3W group were excluded from the ITT and safety analyses because they did not receive any study drug.