Figure 1:

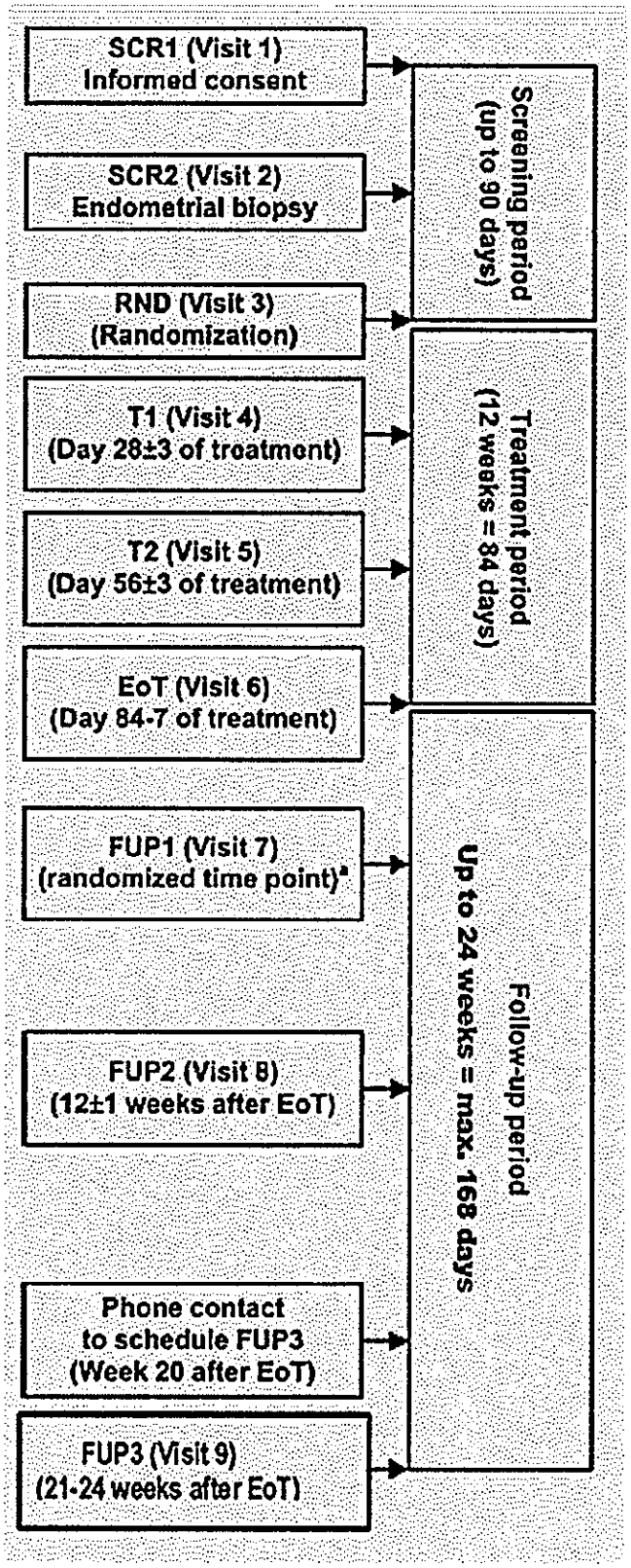

SCR1 (Visit 1)
Informed consent
SCR2 (Visit 2)
Endometrial biopsy
RND (Visit 3)
(Randomization)
T1 (Visit 4)
(Day 28±3 of treatment)
T2 (Visit 5)
(Day 56±3 of treatment)
EoT (Visit 6)
(Day 84-7 of treatment)
FUP1 (Visit 7)
(randomized time point)a
FUP2 (Visit 8)
(12±1 weeks after EoT)
Phone contact
to schedule FUP3
(Week 20 after EoT)
FUP3 (Visit 9)
(21-24 weeks after EoT)
Screening period
(up to 90 days)
Treatment period
(12 weeks = 84 days)
Follow-up period
Up to 24 weeks = max. 168 days

Figure 2:

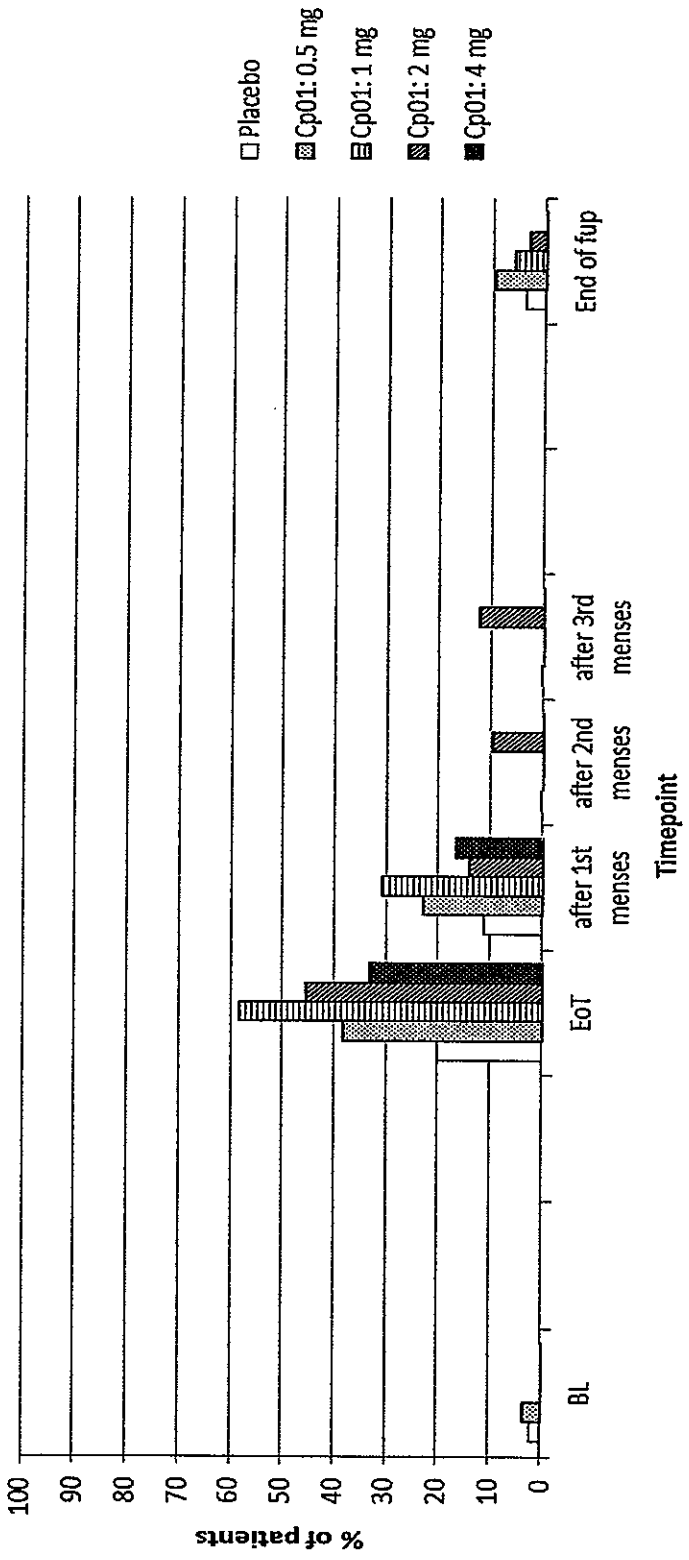

Placebo
Cp01: 0.5 mg
Cp01: 1 mg
Cp01: 2 mg
Cp01: 4 mg
% of patients
100
90
80
70
60
50
40
30
20
10
0
BL
EoT
after 1st menses
after 2nd menses
after 3rd menses
End of fup
Timepoint

Fig 3:

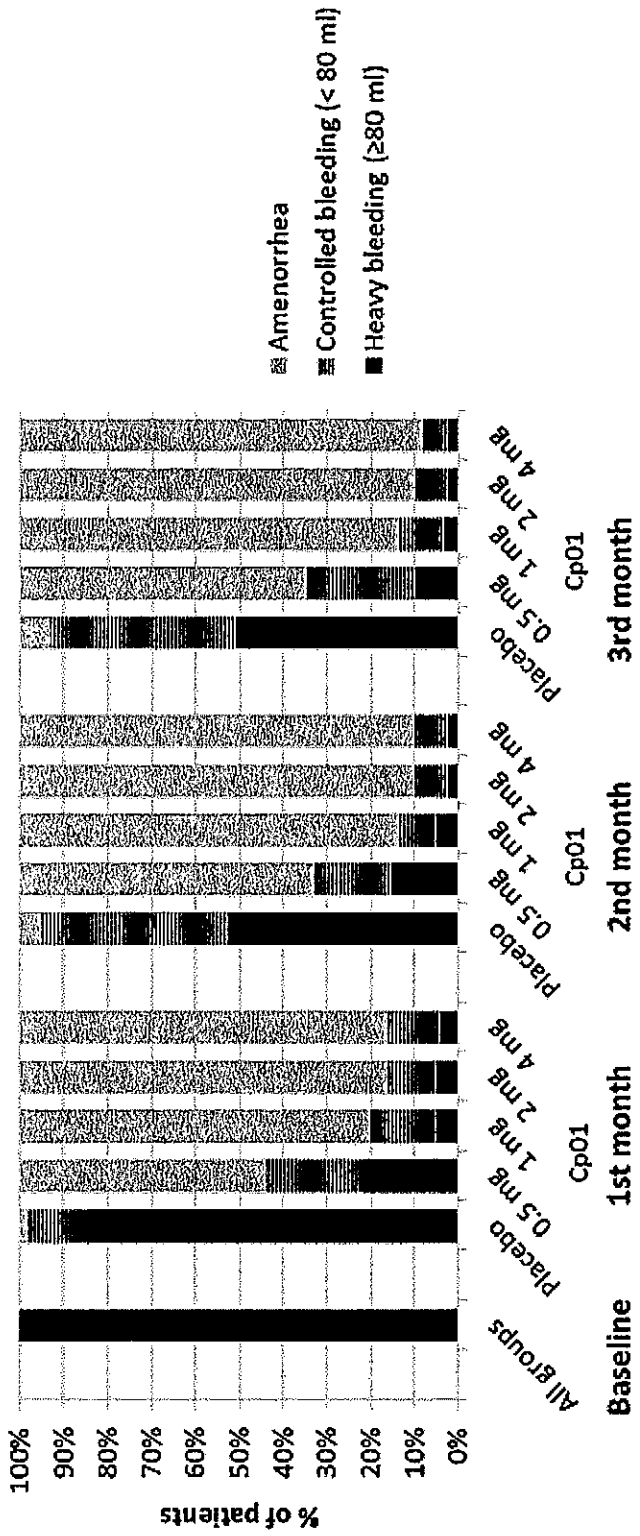

Amenorrhea
Controlled bleeding (< 80 ml)
Heavy bleeding (≥80 ml)
% of patients
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Baseline
All groups
1st month
2nd month
3rd month
Placebo
0.5 mg
1 mg
2 mg
4 mg
CpO1

Figure 4

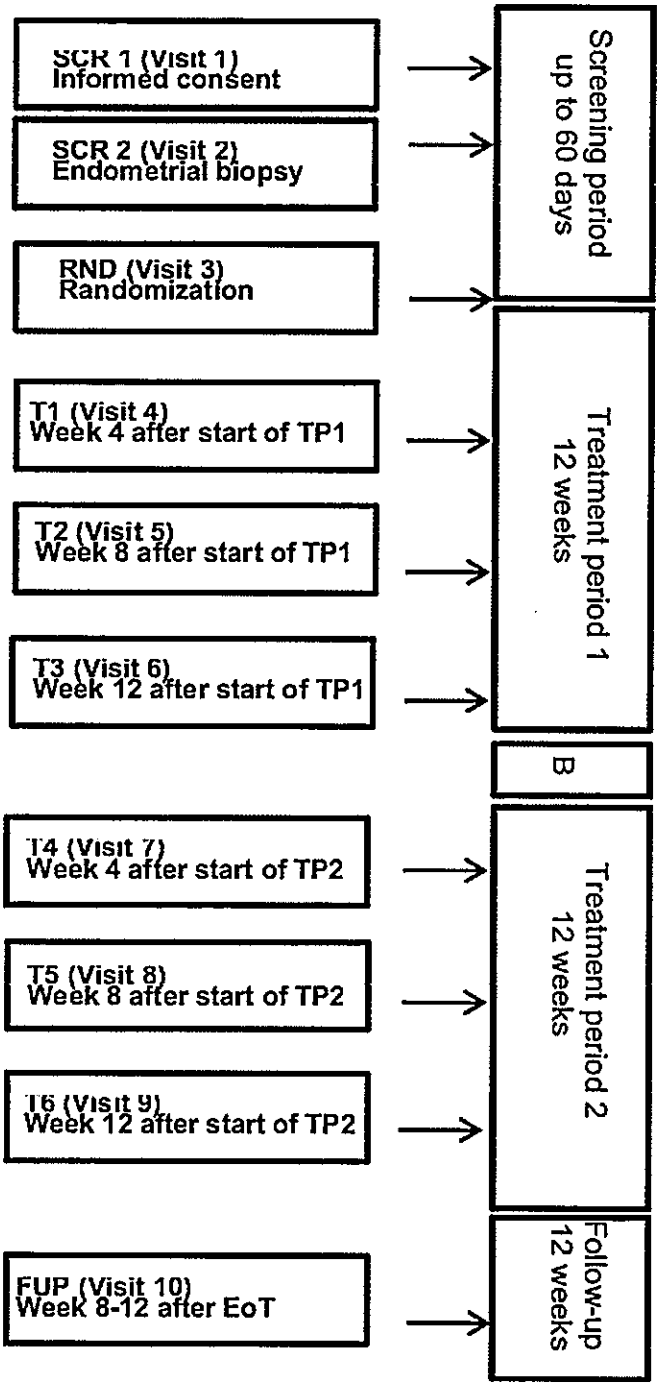

SCR 1 (Visit 1)
Informed consent
SCR 2 (Visit 2)
Endometrial biopsy
RND (Visit 3)
Randomization
Screening period
up to 60 days
T1 (Visit 4)
Week 4 after start of TP1
T2 (Visit 5)
Week 8 after start of TP1
T3 (Visit 6)
Week 12 after start of TP1
Treatment period 1
12 weeks
B
T4 (Visit 7)
Week 4 after start of TP2
T5 (Visit 8)
Week 8 after start of TP2
T6 (Visit 9)
Week 12 after start of TP2
Treatment period 2
12 weeks
FUP (Visit 10)
Week 8-12 after EoT
Follow-up
12 weeks

Figure 5

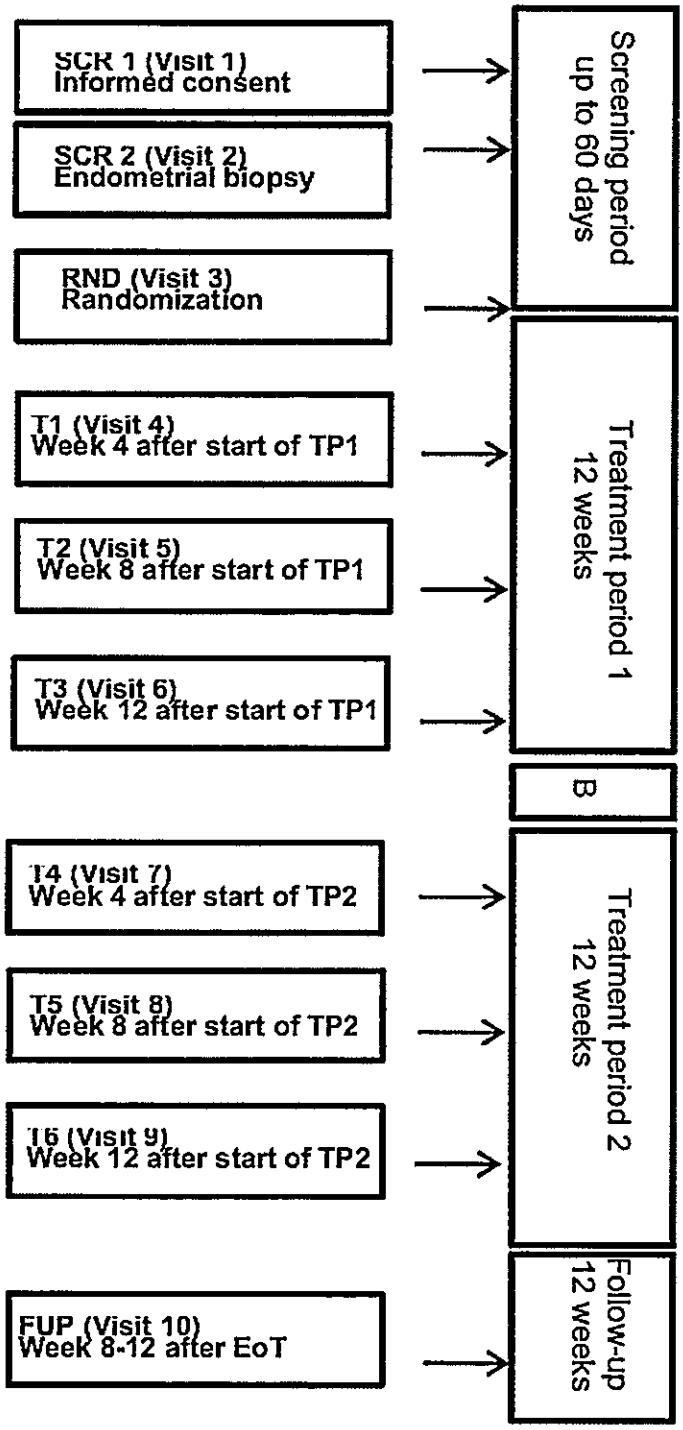

SCR 1 (Visit 1)
Informed consent
SCR 2 (Visit 2)
Endometrial biopsy
RND (Visit 3)
Randomization
Screening period
up to 60 days
T1 (Visit 4)
Week 4 after start of TP1
T2 (Visit 5)
Week 8 after start of TP1
T3 (Visit 6)
Week 12 after start of TP1
Treatment period 1
12 weeks
B
T4 (Visit 7)
Week 4 after start of TP2
T5 (Visit 8)
Week 8 after start of TP2
T6 (Visit 9)
Week 12 after start of TP2
Treatment period 2
12 weeks
FUP (Visit 10)
Week 8-12 after EoT
Follow-up
12 weeks

Figure 6

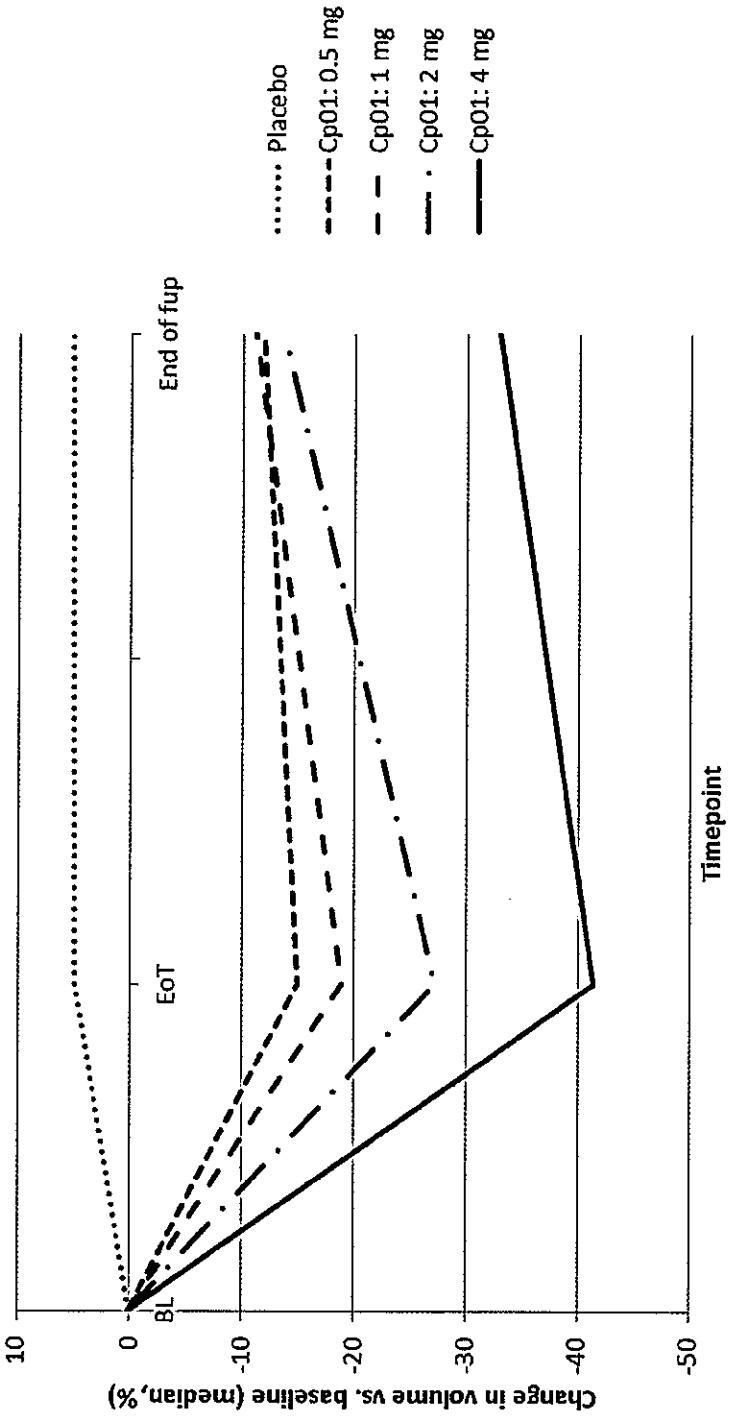
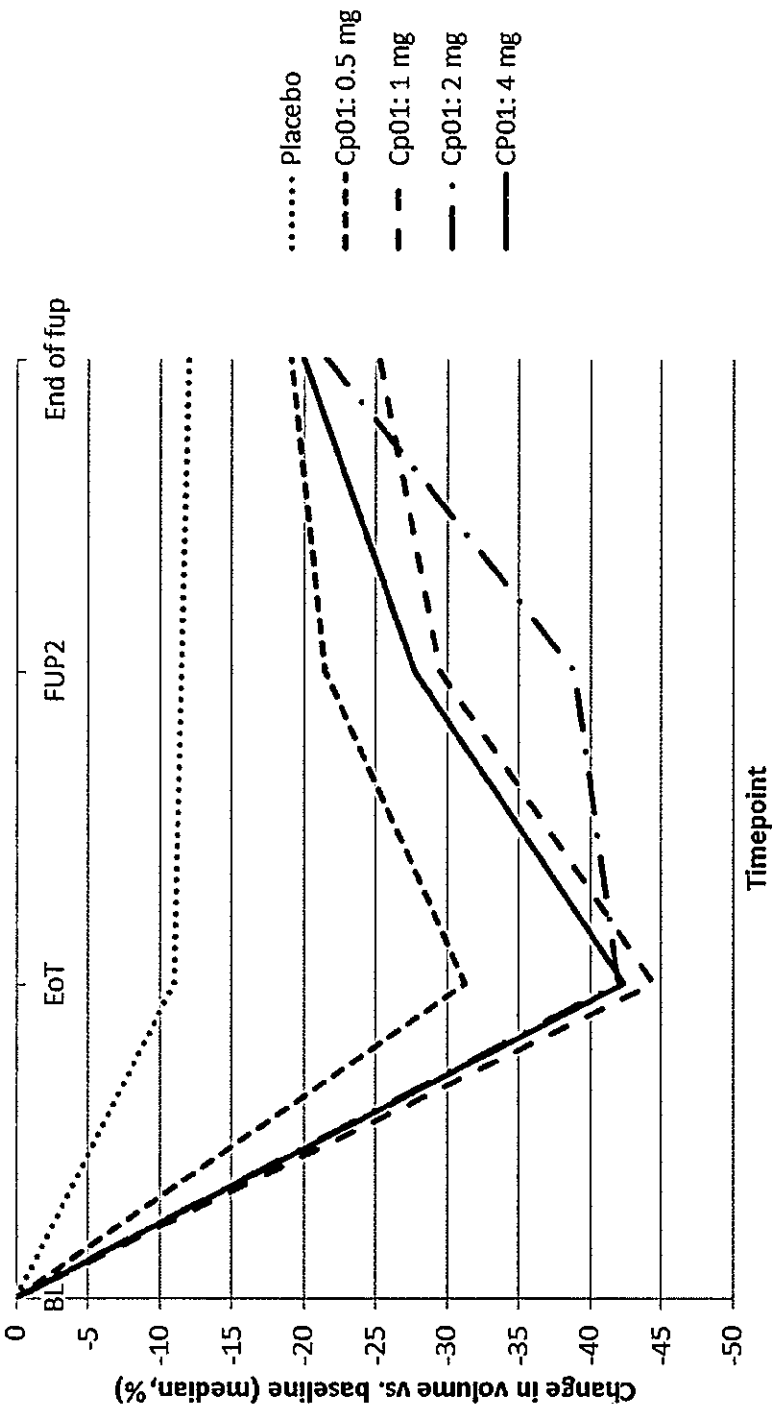

Placebo
CpO1: 0.5 mg
CpO1: 1 mg
CpO1: 2 mg
CpO1: 4 mg
End of fup
EoT
BL
10
0
-10
-20
-30
-40
-50
Change in volume vs. baseline (median,%)
Timepoint

Figure 7


Placebo
Cp01: 0.5 mg
Cp01: 1 mg
Cp01: 2 mg
CP01: 4 mg
Change in volume vs. baseline (median, %)
0
-5
-10
-15
-20
-25
-30
-35
-40
-45
-50
BL
EoT
FUP2
End of fup
Timepoint