Table 1. Summary of study assessments and procedures in the crossover period

	Study period														
	Screening period		Crossover period I							Crossover period II					
			Treatment period NPC-15 or Placebo						Washout	Treatment period Placebo or NPC-15					Washout
	Enrollment	Allocation	Day1[1]	Day 15[1]	Day 16[1]	Day 17[1]	Day 18[1]	Day 19[1]	Day 22–35[2]	Day 1[1]	Day 15[1]	Day 16[1]	Day 17[1]	Day 18[1]	Day 19[1]	Day 22–35[2]
Informed Consent[3]	X															
Baseline data	X															
Enrollment	X															
Prescription			←	—	—	—	—	→			←	—	—	—	→	
UV irradiation[4]				X							X					
MED[4]					X	X	X	X				X	X	X	X	
Melanin index										X						

neurological severity scale score[5]	X															
hearing test[6]	X															
5-meter walk test[7]		X														
Acute skin symptom	X [8]															
Skin cancer	X [8]															
urine test for oxidative stress marker[9]		X						X							X	
Laboratory test	X							X							X	
Secondary sexual characteristics status[10]	X															
Adverse events			←												→	

drowsiness and dizziness		X			X							X				
Body weight		X														
Medication status				X	X	X	X	X		X	X	X	X	X	X	
Concomitantly administered medications[11]		←														→

[1] In the case of five or more consecutive holidays, including weekends and national holidays such as New Year's Eve and Golden Week, the allowable range for the treatment period is ± 3 days, and the allowable range for the washout period after the crossover study period I and II is +22/-4, and ± 4 days, respectively.

[2] Allowance (-3~＋21) is based on the point of day 35.

[3] Consent should be obtained within 12 weeks prior to drug allocation.

[4] Visit tolerance on the UV test day is ± 2; however, evaluation should be made at 24, 48, 72, and 96 hours ± 6 hours after the test day. Re-evaluation is prohibited.

[5] Neurologic severity scale scores will be evaluated in patients aged 3 years or older.

[6] Methods of hearing test (pure-tone audiometry or conditioned play audiometry) will be recorded in the medical records.

[7] The 5-meter walk test will be conducted including the patients who wear braces when the principal/participating investigator deems the patient can tolerate the test. The presence or absence of brace or the type of brace used will be recorded in the medical records. When the patient wears the brace, the tests at visit 1 and Visit 305 will be conducted using the same brace as far as possible, and if the brace is changed, the kinds of brace and the reason for the change of brace will be described in the medical records.

[8] Data will be collected within 62 weeks prior to administration of the study drug.

[9] Laboratory urine test: oxidative stress markers (Malondialdehyde, 8-hydroxy-2-deoxyguanosine, Hexanoyl-Lys) and N-acetyl 5-methoxytryptamine metabolites (6-sulfatoxymelatonin).

[10] Confirmation of secondary sexual characteristics status and measurement of prolactin levels in blood. To be performed on patients between 10 and 17 years of age.

[11] Four weeks prior to the initiation of the study drug.