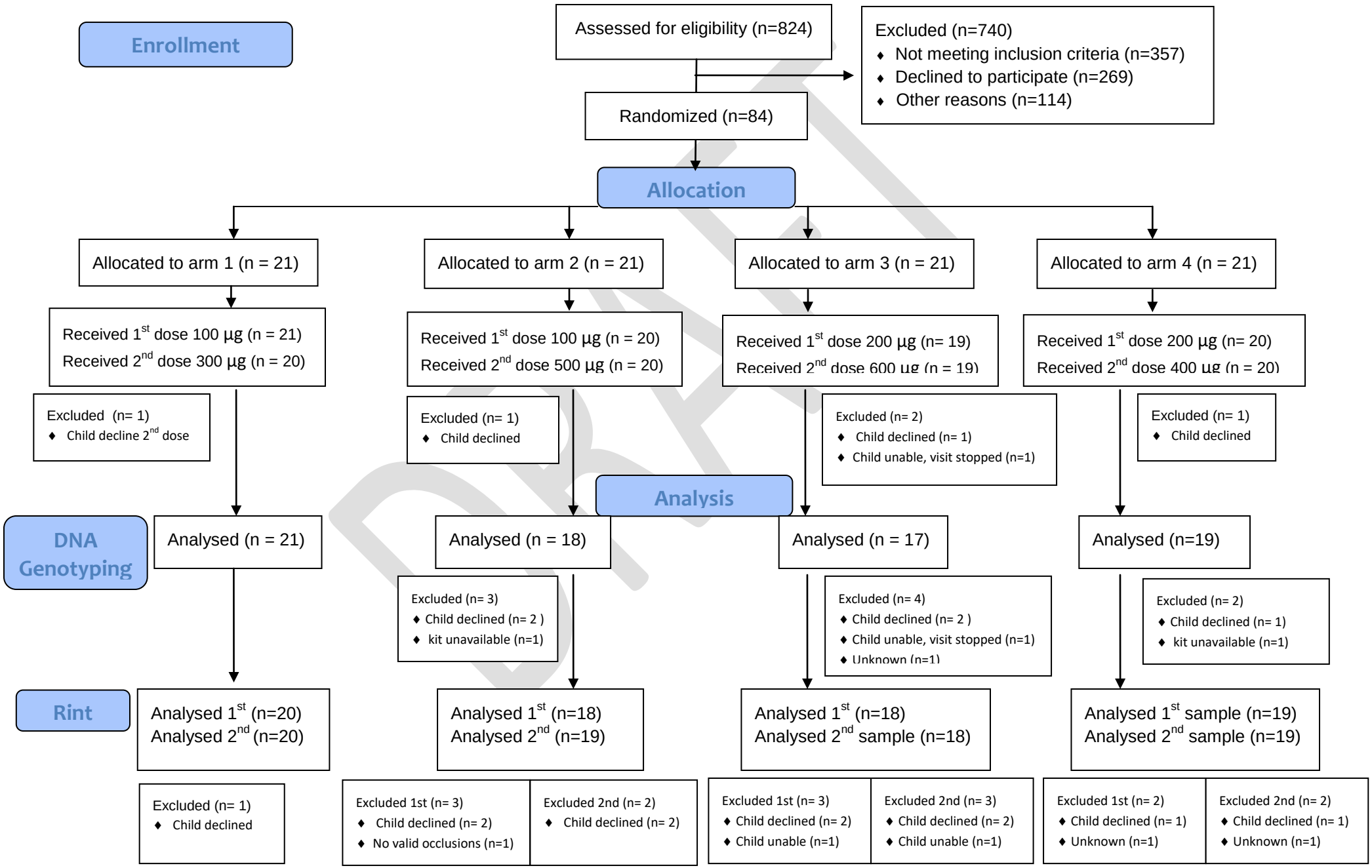
CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram for OpSal



Results from primary analysis of OpSal (N=84)

Table 1: Primary analysis (a) – effect of dosing schedule on Rint measurement after 1st dose (N=75)

Comparison	Ratio of means	99% confidence interval	*p-value
200 µg vs. 100 µg	0.950	(0.862, 1.046)	0.162

* Significance threshold p<0.01

Table 2: Primary analysis (b) – effect of dosing schedule on Rint measurement after 2nd dose (N=75)

Comparison	Ratio of means	99% confidence interval	*p-value
100 µg + 500 µg vs. 100 µg + 300 µg	0.990	(0.855, 1.145)	0.849
200 µg + 600 µg vs 100 µg + 300 µg	0.968	(0.833, 1.126)	0.575
200 µg + 200 µg vs. 100 µg + 300 µg	0.904	(0.781, 1.046)	0.070

* Significance threshold p<0.01

Table 3: Effect of interaction between A16 genotype and dosing schedule on first Rint measurement (N=73)

Comparison	Ratio of means	95% confidence interval	*p-value
200 µg vs. 100 µg	0.950	(0.841, 1.074)	0.410
(Arg/Arg & Arg/Gly) vs. Gly/Gly	1.073	(0.966, 1.191)	0.183
(200 µg vs. 100 µg) × (Arg/Arg & Arg/Gly vs. Gly/Gly)	1.015	(0.873, 1.181)	0.840

* Significance threshold p<0.05

Table 4: Effect of interaction between A16 genotype and dosing schedule on second Rint measurement (N=73)

Comparison	Ratio of means	95% confidence interval	*p-value
(100 µg + 500 µg) vs. (100 µg + 300 µg & 200 µg + 200 µg)	1.097	(0.925, 1.301)	0.284
(200 µg + 600 µg) vs. (100 µg + 300 µg & 200 µg + 200 µg)	1.038	(0.863, 1.248)	0.691
(Arg/Arg & Arg/Gly) vs. Gly/Gly	1.112	(0.990, 1.249)	0.074
(600 µg vs. 400 µg) x (Arg/Arg & Arg/Gly vs. Gly/Gly)	0.908	(0.735, 1.121)	0.363
(800 µg vs. 400 µg) x (Arg/Arg & Arg/Gly vs. Gly/Gly)	0.969	(0.775, 1.211)	0.777

* Significance threshold p<0.05

Results from primary analysis of OpSal (N=84) & Doresi (N=35) data combined (N=119)

Table 5: Primary analysis (a) – effect of dosing schedule on Rint measurement after 1st dose (N=110)

Comparison	Ratio of means	99% confidence interval	*p-value
200 µg vs. 100 µg	0.95	(0.87, 1.03)	0.085

* Significance threshold p<0.01

Table 6: Primary analysis (b) – effect of dosing schedule on Rint measurement after 2nd dose (N=110)

Comparison	Ratio of means	99% confidence interval	*p-value
100 µg + 500 µg vs. 100 µg + 300 µg	0.97	(0.86, 1.09)	0.466
200 µg + 600 µg vs 100 µg + 300 µg	0.91	(0.81, 1.02)	0.027
200 µg + 200 µg vs. 100 µg + 300 µg	0.90	(0.80, 1.01)	0.014

* Significance threshold p<0.01

Table 7: Effect of interaction between A16 genotype and dosing schedule on first Rint measurement (N=108)

Comparison	Ratio of means	95% confidence interval	*p-value
200 µg vs. 100 µg	0.93	(0.84, 1.03)	0.151
(Arg/Arg & Arg/Gly) vs. Gly/Gly	1.02	(0.93, 1.11)	0.703
(200 µg vs. 100 µg) × (Arg/Arg & Arg/Gly vs. Gly/Gly)	1.05	(0.92, 1.19)	0.493

* Significance threshold p<0.05

Table 8: Effect of interaction between A16 genotype and dosing schedule on second Rint measurement (N=108)

Comparison	Ratio of means	95% confidence interval	*p-value
(100 µg + 500 µg) vs. (100 µg + 300 µg & 200 µg + 200 µg)	1.01	(0.87, 1.16)	0.934
(200 µg + 600 µg) vs. (100 µg + 300 µg & 200 µg + 200 µg)	0.92	(0.80, 1.05)	0.195
(Arg/Arg & Arg/Gly) vs. Gly/Gly	1.02	(0.93, 1.11)	0.707
(600 µg vs. 400 µg) x (Arg/Arg & Arg/Gly vs. Gly/Gly)	1.01	(0.85, 1.20)	0.923
(800 µg vs. 400 µg) x (Arg/Arg & Arg/Gly vs. Gly/Gly)	1.06	(0.90, 1.25)	0.487

* Significance threshold p<0.05

Adverse Events

There were no adverse events associated with this study.