Randomized
N=301

Prophylactic group
n=148

Received infant
dose 1
n=148

Received infant
dose 2
n=145

Received infant
dose 3
n=145

Received toddler
dose
n=139

Included in
deroprotocol
efficacy
population
n=116

Control group
n=153

Received infant
dose 1
n=152

Received infant
dose 2
n=151

Received infant
dose 3
n=151

Received toddler
dose
n=147

Included in
eroprotocol
efficacy
population
n=129

1 did not sign informed consent

Withdrawals
Lost to follow-up, n=7
Parent request, n=1
Investigator request, n=1

ITT population N=147
No temperature recorded n=1

Per protocol population
32 excluded* from the randomized group
- Had <75% of required temperature measurements at any dose, n=41
- Did not receive vaccine at dose 2, n=3
- Did not receive vaccine at dose 3, n=3
- Did not receive toddler dose, n=9
- Did not receive all required paracetamol at dose 1, n=2
- Did not receive all required paracetamol at dose 2, n=2
- Did not receive all required paracetamol at dose 3, n=1
- Did not receive all required paracetamol at dose 4, n=2
- Received prohibited vaccine (MMR) prior to post-toddler follow-up, n=1
- Not included in ITT population, n=1
- Enrolled in another clinical trial between visits 4 and 5, n=1
- Received paracetamol prior to vaccination, n=1
- Forced randomization assignment, n=1
- Not 335-455 days old at dose 4, n=2

ITT population N=152
Not eligible (no informed consent) n=1

Withdrawals
Lost to follow up, n=2
Parent request, n=2
Protocol violation, n=2

Per-protocol population
24 excluded* from the randomized group
- Had <75% of required temperature measurements at any dose, n=32
- Did not receive vaccine at dose 1, n=1
- Did not receive vaccine at dose 2, n=2
- Did not receive vaccine at dose 3, n=2
- Did not receive toddler dose, n=6
- Not eligible, n=3
- Received prohibited vaccine (MMR) prior to post-toddler follow-up, n=1
- Not included in ITT population, n=1
- Enrolled in another clinical trial between visits 4 and 5, n=1
- Birth weight <2,500 g, n=1
- Had febrile seizure between infant series and toddler dose, n=1
- Older than 112 days at enrollment, n=1
- Not 335-455 days old at dose 4, n=3