**Participant Flow**

**Figure 2. Flow of patients during study**

**255**

Patients admitted to Winter Campaign 2013

60

eligible for study

29 assigned to CG

31 assigned to PG

6 excluded:

1 intubation/sepsis

1 intubation/SRD

1 intubation/BPD

1 CLD

1 BPD

1 registration failure

7 excluded:

1 intubation/sepsis

1 intubation/SRD

1 withdrawal of consent

1 CLD

1 wrong age

1 registration failure

1 prematurity

**23**

Included in analysis

**24**

Included in analysis

CG: Control Group, PG: Protocol Group, SRD Severe Respiratory Disease, BPD: Bronchopulmonary Dysplasia, CLD: Chronic Lung Damage.

**Baseline Characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristics of sample on admission** | | | |
|  | Intervention | |  |
| **Characteristics** | GC (mean, SD, range) | GP (mean, SD, range) | p-value |
| **Age (months)** | 9.7 ± 5.7 (3-23) | 9.3 ± 4.3 (3-20) | 0.783 |
| **Severity on admission (MWS)** | 4.8 ± 0.7 (4-6.5) | 5.7 ± 0.83 (4.1-7.5) | <0.001 |
| **Sex   f (%)**    **Female**  **Male** | 14 (61)  9 (39) | 7 (29)  17 (71) | 0.029 |
| **Diagnoses f (%)**    **PNA RSV**  **PNA**  **OBS** | 17 (74)  5 (19)  1 (7) | 15 (63)  6 (25)  3 (12) | 0.993 |
| **CG (control group), PG (protocol group), f (frequency), PNA (pneumonia), RSV (respiratory syncytial virus), OBS (obstructive bronchitis syndrome).** | | | |

**Outcome Measures**

|  |  |  |  |
| --- | --- | --- | --- |
| **Comparison of impact indicators by intervention** | | | |
| **Impact indicators** | CG (mean, SD) | PG (mean, SD) | p-value |
| **Hours of hospitalization** | 207.5 ±  244.1 | 187.4 ±  77.9 | 0.709 |
| **Hours of NIV** | 96.1 ± 50.4 | 90.7 ±  43.8 | 0.695 |
| **Hours of additional oxygen post NIV** | 39.6 ±  44.4 | 34.6 ±  40.4 | 0.689 |
| **CG (control group), PG (protocol group), f (frequency), NIV (Noninvasive ventilation).** | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Comparison of secondary outcomes by intervention** | | | |
| **Impact indicators** | CG (mean, SD) | PG (mean, SD) | p-value |
| **MWS at 1 hour after NIPPV start** | 3.7 ± 0.18 | 4.46 ± 0.23 | 0.021 |
|  | 1 hour of NIPPV (mean, SD) | 24 hours of NIPPV (mean, SD) | p-value |
| **SAFI index (Protocol group)** | 313 ± 14.92 | 272.788 ± 11.1 | 0.030 |
|  | Baseline (mean, SD) | 1 hour of NIPPV (mean, SD) | p-value |
| **MWS (Protocol group)** | 5.65 ± 0.17 | 4.46 ± 0.23 | 0.000 |
|  | 1 hour of NIPPV (mean, SD) | 24 hours of NIPPV (mean, SD) | p-value |
| **MWS (Protocol group)** | 4.46 ± 0.23 | 2.20 ± 0.16 | 0.000 |
|  | 24 hour of NIPPV (mean, SD) | 4 hours of CPAP (mean, SD) | p-value |
| **MWS (Protocol group)** | 2.20 ± 0.16 | 1.86 ± 0.13 | 0.013 |
|  | CG (f, %) | PG (f,%) | p-value |
| **Proportion of intubation** | 3/29, 10.3 | 2/31, 6.5 | 0.600 |

**Adverse Events**

There were no adverse events associated with this trial.